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No. 08-

IN THE

Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.
D/B/A CHICKEN OF THE SEA,
Petitioner,

v.

DEBORAH FELLNER,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether state-law tort claims based upon failure to warn of the risks of methylmercury in tuna fish products are preempted by the Federal Food, Drug, and Cosmetics Act and regulatory actions of the Food and Drug Administration, including a written determination that state-law warning requirements concerning methylmercury in tuna products are preempted by federal law and denial of a petition to require such warnings.

2. Whether a "presumption against preemption" applies in conflict preemption cases.

PARTIES TO THE PROCEEDING AND RULE 29.6 DISCLOSURE

The parties to the proceeding are as follows: Petitioner Tri-Union Seafoods, L.L.C., d/b/a Chicken of the Sea International, was the defendant in the district court and the appellee in the court of appeals. Respondent Deborah Fellner was the plaintiff in the district court and the appellant in the court of appeals.

Tri-Union Seafoods, L.L.C., d/b/a Chicken of the Sea International, is a California limited liability company. Tri-Union Seafoods, L.L.C. is a wholly owned subsidiary of Thai Union International, Inc., a California corporation that has not issued shares or securities that are publicly traded. No publicly owned company owns ten percent or more of the stock of Thai Union International, Inc.

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The opinion of the court of appeals, App., *infra*, 1a-37a, is reported at 539 F.3d 237. The opinion of the district court, App., *infra*, 38a-54a, is unreported.

JURISDICTION

The judgment of the court of appeals was entered on August 19, 2008. App., *infra*, 1a. The court of appeals denied a petition for rehearing on September 15, 2008. *Id.* at 55a-56a. On December 5, 2008, Justice Souter extended the time to file a petition for a writ of certiorari to January 13, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the United States Constitution provides, in relevant part:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. Art. VI.

Relevant provisions of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et seq.*, are reprinted in the Appendix. App., *infra*, 57a-62a.

STATEMENT

1. FDA's Regulation Of Food Safety. Congress has entrusted the Food and Drug Administration ("FDA") with responsibility to protect the safety of food products in the United States. *See* Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et. seq.* Under the FDCA, FDA has broad authority to regulate the labels of food products. *See* 21 U.S.C. § 343 *et seq.* In addition, the FDCA prohibits the transmission in interstate commerce of food that is adulterated or misbranded and authorizes FDA to enforce those prohibitions. *See* 21 U.S.C. §§ 343(a)(1) & 321(n).

FDA's basic approach to regulating food safety is to (1) prohibit the marketing of foods that may pose health risks and (2) develop tolerance and "action" levels to limit the amount of potentially dangerous substances in foods. *See, e.g.*, 42 Fed. Reg. 52,814 (Sept. 30, 1977). If foods exceed tolerance or action levels established by FDA, the agency may find that they are "adulterated" in violation of the FDCA.

In exercising its authority to regulate food labeling, FDA has opted not to require warnings for every ingredient or product that has possible deleterious effects. Instead, FDA relies primarily on disclosure of ingredient and nutrition information on food labels and directs manufacturers to provide warnings on labels only in exceptional

circumstances.[1] FDA has adopted this regulatory approach to avoid overexposing consumers to warnings, which could confuse consumers or cause them to ignore all such statements. *See, e.g.*, 63 Fed. Reg. 37,030, 37,035 (July 8, 1998) (concluding that "too many warning labels on foods could result in loss of consumer credibility and effectiveness"); 44 Fed. Reg. 59,509, 59,513 (Oct. 16, 1979) ("A requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant . . . would apply to many, perhaps most foods in a supermarket. Such warnings would be so numerous they would confuse the public, would not promote informed consumer decisionmaking, and would not advance the public health.").

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[1] For example, FDA requires that any food containing the sweetener aspartame must include the following statement on the label: "Phenylketonurics: contains phenylalanine." 21 C.F.R. § 172.804(d)(2). Juices that have not been pasteurized must include the following statement on the label: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious injury in children, the elderly, and persons with weakened immune systems." 21 C.F.R. § 101.17(g). Food products that derive more than 50 percent of their total caloric value from whole protein, protein hydrolysates, amino acid mixtures, or a combination of these, and are represented for use in weight reduction, must include the following statement on the label: "WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women." 21 C.F.R. § 101.17(d).

In 1990, Congress amended the FDCA to expressly preempt certain state requirements concerning nutrition labeling, food standards of identity, and other label requirements. Nutrition Labeling and Education Act of 1990 ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353, 2364. Section 6(c) of the NLEA, entitled "Construction," provides that the express preemption provisions should not be construed to preempt state food warning requirements, but that nothing in the 1990 amendments should be construed to affect preemption, "express or implied," of any state requirement under the Constitution, any provision of the FDCA not amended by the NLEA, or any other federal law. 104 Stat. at 2364.

2. FDA's Regulation Of Methylmercury In Fish. FDA has studied the risks of methylmercury in fish for decades. In 1979, FDA determined that a methylmercury action level of 1.0 part per million is safe for seafood. 44 Fed. Reg. 3,990, 3,993 (Jan. 19, 1979). In the ensuing decades, FDA has engaged in an extensive program to evaluate the risks of mercury in fish. Based on this evaluation, FDA has taken a series of regulatory actions, including: (1) issuing consumer advisories targeted at vulnerable subpopulations concerning the risks of methylmercury in fish, (2) rejecting a petition to require product-label warnings about the risks of mercury in fish, and (3) issuing a written determination that state-law warning requirements concerning the risks of mercury in tuna are preempted by federal law.

a. *FDA's Consumer Advisories.* FDA first issued an advisory on methylmercury in fish in 1995. The 1995 Advisory, entitled "Is Mercury in Fish a Safety Concern?," stated: "FDA food specialists say that eating a variety of types of fish, the normal pattern of consumption, does not put anyone in danger of mercury poisoning. It is when people eat fad diets—frequently eating only one type of food or a particular species of fish—that they put themselves at risk." C.A. App. A155. The 1995 Advisory stated that "consumption advice is unnecessary for the top 10 seafood species," including "canned tuna." *Id.*

The current Advisory, entitled "What You Need to Know About Mercury in Fish and Shellfish," was issued jointly by FDA and the Environmental Protection Agency ("EPA") in 2004. EPA-823-R-04-005, http://www.cfsan.fda.gov/~dms/admehg3.html (March, 2004) ("2004 Advisory"). The 2004 Advisory states that "[f]ish and shellfish are an important part of a healthy diet." *Id.* They "contain high-quality protein and other essential nutrients, are low in saturated fat, and contain omega-3 fatty acids." Because "[a] well-balanced diet that includes a variety of fish and shellfish can contribute to heart health and children's proper growth and development," FDA and EPA advise that "women and young children in particular should include fish or shellfish in their diets due to the many nutritional benefits." *Id.*

The Advisory further states that "nearly all fish and shellfish contain traces of mercury." FDA and EPA advise that, "[f]or most people, the risk from mercury by eating fish and shellfish is not a

health concern." The agencies note, however, that "some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system." *Id.*

FDA and EPA make three principal recommendations for women and young children:

> (1) Do not eat certain fish that contain high levels of mercury (shark, swordfish, king mackerel, and tilefish);
>
> (2) Eat up to 12 ounces a week of a variety of fish and shellfish that are lower in mercury (including canned light tuna), or up to 6 ounces per week of albacore tuna; and
>
> (3) Check local advisories concerning the safety of fish caught by family and friends in local waters, and if no advice is available eat up to 6 ounces per week of fish you catch from local waters.

b. *FDA's Denial of the Martek Petition.* In September 2004, FDA issued a decision allowing qualified health claims that "[s]upportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease."[2] In deciding to allow such

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[2] Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Martin J. Hahn, Hogan & Hartson, LLP (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0002-vol13.pdf ["FDA Martek Petition (continued...)

claims, FDA considered and rejected a petition filed by Martek Biosciences Corporation ("Martek") seeking to require that any qualified health claim concerning fish products, including tuna products, should be accompanied by an advisory statement recommending a limited weekly intake for a vulnerable population of pregnant women, women of childbearing age, nursing mothers, and young children.

The Martek Petition was submitted in accordance with FDA's regulations regarding petitions by interested persons, codified at 21 C.F.R. §§ 10.30, 10.33, 10.35, and with FDA's interim procedures for qualified health claims. FDA Martek Petition Denial at 1-2 & n.1. Those procedures include notice and opportunity for public comment, scientific review, consultation with other federal agencies, the issuance of a written regulatory decision, and the possibility of agency reconsideration. FDA Center for Food Safety & Applied Nutrition, Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, http://www.cfsan.fda.gov/~dms/hclmgui3.html. In response to the Martek Petition, FDA received and considered comments from "industry, a professional organization, and an individual." FDA Martek Petition Denial at 2.

Denial"]; Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Jonathan W. Emord, Emord & Associates, PC (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0001-vol13.pdf.

In denying the Martek Petition, FDA explained that because of limited space, a warning label could not provide the "level of clarity and detail" in FDA's advisory statements. *Id.* at 29. In addition, FDA noted, different labels in line with FDA guidance regarding particular fish species and locally caught versus commercially raised fish could cause consumer confusion. *Id.* Moreover, FDA research suggests that "a label statement that reaches the public at large can also have unintended adverse public health consequences" due to deterring people outside the target groups from eating any fish at all. *Id.* The agency stated:

> FDA disagrees with the petitioners' contention that the omega-3 fatty acid qualified health claim should be accompanied by a product label statement about mercury content of fish and possible harmful health effects to the vulnerable population of pregnant women, women who might become pregnant, nursing mothers, and young children. For some time, FDA has been addressing the issue of reducing the exposure to the harmful effects of mercury by communicating with the target population . . . through the use of consumer advisories. . . .

Id. at 28. The agency concluded, *"FDA has decided that it is preferable not to use a label statement about mercury."* *Id.* at 29 (emphasis added).

c. *FDA's Preemption Letter.* In August 2005, the Commissioner of the FDA issued a letter to the California Attorney General concerning warning labels on tuna products in response to litigation brought by the Attorney General of California under California's Proposition 65.[3] Letter to Bill Lockyer, Attorney General of the State of California, http://www.cfsan.fda.gov/~dms/fl-ltr65.html. The letter explains that, after analyzing the research on methylmercury in tuna, FDA has adopted and implemented a regulatory approach that is intended to balance the health benefits of consuming fish against the potential risks to a subpopulation that includes pregnant women, women who may become pregnant, nursing mothers, and young children.

The FDA letter explains that, "rather than requiring warnings for every single ingredient or product with possible deleterious effects, FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information. . . ." *Id.* FDA has required warnings "only in those instances where there is clear evidence of a hazard, in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements,

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[3] Proposition 65 provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." Cal. Health & Saf. Code § 25249.6. Proposition 65 does not apply to "[a]n exposure for which federal law governs warning in a manner that preempts state authority." Cal. Health & Saf. Code § 25249.16

and hence creating a far greater public health concern." *Id.*

The FDA Commissioner explained the reasons for FDA's regulatory decision to issue consumer advisories rather than requiring warnings on product labels:

> First, consumer advisories are communicated to the target audience directly, rather than to all consumers. Second, FDA believes that the advisory approach is more effective than a product label statement in relaying the complex messages about mercury in seafood. Third, a label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results have suggested that people who are not in the target audience might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish and possible harmful health effects to the targeted audience.

Id. The FDA letter noted that these same concerns led it to reject the Martek petition's proposal that a mercury warning should accompany qualified health claims about omega-3 fatty acids. *Id.* For these reasons, FDA concluded that it would be impossible to comply with state law requiring a warning on the product label concerning methylmercury in fish and

at the same time comply with FDA's regulatory requirements. *Id.*

3. This Case. Respondent brought this action against Petitioner in New Jersey state court seeking damages for harm she allegedly sustained as a result of consuming tuna fish. She alleges that from 1999 to 2004, her diet consisted almost exclusively of Chicken-of-the-Sea tuna fish products. She further alleges that, as a result of her consumption of tuna fish, she suffered injuries from mercury poisoning. Respondent asserts her claim that Petitioner failed to warn of the risks of consuming tuna fish under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 *et seq.*, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*, and common law fraud. App., *infra*, 38a-39a. After removing the case to federal court (based upon diversity of citizenship), Petitioner filed a motion to dismiss for failure to state a claim, contending that Respondent's state-law failure-to-warn claim is preempted by federal law.

4. The District Court's Decision. The district court (D.N.J., Cavanaugh, J.) granted Petitioner's motion to dismiss. App., *infra*, 38a-54a. The court concluded that there is "a pervasive federal regulatory scheme implemented by and through the FDA." App., *infra*, 44a. The court cited FDA's determination that additional warnings concerning the risks of methylmercury in tuna fish products required under California law would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." App.,

infra, 45a (quoting FDA letter at 1). The court explained that FDA, after many years of study, "has chosen to issue an advisory rather than to require a warning on fish and shellfish labels for several reasons." *Id.* (quoting FDA letter at 2). The court further observed that FDA's Consumer Advisory "specifically rejected the notion that warning labels should be included on cans of tuna." *Id.*

The district court framed the "essential issue" as "whether the FDA's regulatory scheme as explained and embodied in the FDA Letter, Advisory and other materials is entitled to deference from this Court." App., *infra*, 47a. The court rejected Respondent's argument that the FDA letter is not entitled to judicial deference because it is "too informal" and "appears to have been solicited for the express purpose of derailing litigation against [Petitioner] and other seafood companies." *Id.* The court noted that "it is not uncommon for the FDA to specifically choose the issuance of an advisory rather than an official warning." *Id.* at 50a. Moreover, the court reasoned, courts do not require "'a specific formal agency statement identifying conflict in order to conclude that such a conflict in fact exists.'" *Id.* (quoting *Geier* v. *Honda Motor Co.*, 529 U.S. 861, 884-85 (2000)).

The court found that FDA's Consumer Advisory and an accompanying Backgrounder, which were released before litigation began, "evidence a clear effort by the FDA and EPA to encourage the continued public consumption of fish." App., *infra*, 49a. The FDA letter "only crystallizes the already transparent intent of the FDA to preempt state law

that might interfere with the FDA's concern that warnings on tuna products may upset the desired balance between informing consumers of both the benefits and risks of fish consumption." *Id.* at 51a.

The district court declined to "turn a blind eye to the evidence of the FDA's ten-year deliberately balanced approach to the issue of methylmercury in fish." *Id.* at 53a. Because "it would be impossible for [Petitioner] to comply with the FDA and New Jersey law," the court granted Petitioner's motion to dismiss.[4] *Id.* at 52a.

5. The Court Of Appeals' Decision. The court of appeals (Sloviter, Smith & Stapleton, JJ.), reversed. The appellate court recognized that "federal regulations as well as statutes can establish federal law having preemptive force." App., *infra*, 9a (citing *New York* v. *FCC*, 486 U.S. 57, 63 (1988)). The court also recognized that, "in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority" may have preemptive effect outside the context of notice-and-comment rulemaking. *Id.* For example, the court of appeals has held that state-law claims against drug manufacturers for failing to warn that certain prescription drugs created an increased risk of suicidality are preempted, based upon FDA's approval of the drugs' labeling both at the time the drugs were first marketed and thereafter. *Id.* (citing

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[4] The district court dismissed plaintiffs' common law fraud claim on the ground that it violated New Jersey's "single cause of action rule." App., *infra*, 54a.

Colacicco v. *Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008)).[5] In *Colacicco*, the court determined that FDA had "'clearly and publicly stated its position [regarding the propriety of the warning in the pertinent circumstances] prior to the prescriptions and deaths at issue.'" App., *infra*, 11a (quoting *Colacicco*, 521 F.3d at 271 (bracketed text in original)). FDA's actions, the *Colacicco* court held, "established a policy against the sought-after warnings applicable not only to the immediate participants but also to others in like circumstances." App., *infra*, 11a.

The court of appeals observed that a federal agency's decision not to regulate will not preempt state law absent an "'authoritative message of federal policy'" that an issue is to remain free of state regulation. *Id.* at 16a (quoting *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 67 (2002)). The court concluded that FDA's actions in this case were "less formal" than the agency's actions in *Colacicco*, and for that reason do not preempt state law. The court stated that it had "found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption." App., *infra*, 13a.

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[5] The court of appeals disagreed with suggestions by some courts that notice-and-comment rulemaking is the only type of federal agency action that can preempt state law. App., *infra*, 9a (citing *Good* v. *Altria Group*, 501 F.3d 29, 51-52 (1st Cir. 2007), *aff'd on other grounds*, 129 S. Ct. 538 (2008)).

The court of appeals declined to defer to FDA's Advisory and Backgrounder on the ground that they "are not agency interpretations of regulations claimed to preempt state law but rather are the very agency actions which are claimed to preempt state law." *Id.* at 23a. The court acknowledged that the Commissioner's letter is entitled to "consideration" under *Geier*, but stated that "we do not find the letter persuasive" because the views expressed in the letter "have not been shown to be the product of any agency proceeding," "were not expressed at the time" the agency took the actions at issue or when Respondent's damages allegedly arose, and are "not self-evident from the nature of the actions themselves." *Id.* at 23a-24a.

In reversing the district court, the court of appeals applied a "presumption against preemption." *Id.* at 18a-21a. In the court's view, "a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product" is "squarely within the realm of traditional state regulation." *Id.* at 19a-20a. The court of appeals acknowledged that "the Supreme Court has applied the presumption in few conflict preemption cases of late," but stated that it will continue to apply the presumption "until the Supreme Court provides guidance to the contrary." *Id.* at 21a.

REASONS FOR GRANTING THE WRIT

The court of appeals' holding that FDA's regulatory actions with respect to mercury in fish products were not sufficiently formal to preempt state law merits further review for three reasons.

First, the decision conflicts with a decision of the California Supreme Court according preemptive force to similar FDA actions. The court of appeals' refusal to defer to FDA's regulatory actions embodied in its Consumer Advisories, the denial of the Martek Petition, and the FDA letter to the California Attorney General is also inconsistent with this Court's precedent, which recognizes that agency action need not rise to the level of formality that attends notice and comment procedures to carry preemptive force. Moreover, the court of appeals disregarded the Martek petition, which was the subject of public notice and comment.

Second, the court of appeals has placed Petitioner in an untenable position by subjecting it to potential liability under state law for failing to include a warning label that in FDA's view would render its products misbranded under federal law.

Third, the court of appeals' reliance on a presumption against preemption conflicts with the decisions of other federal courts of appeals, which have rejected the presumption in conflict preemption cases.

I. The Court Of Appeals' Decision Conflicts With A California Supreme Court Decision Holding That Similar Agency Actions Are Sufficient To Preempt State Law.

The court of appeals' decision conflicts with a decision of the California Supreme Court holding that similar FDA actions are sufficient to preempt state law. In *Dowhal* v. *SmithKline Beecham*

Consumer Healthcare, 88 P.3d 1 (2004), the California Supreme Court unanimously held that federal law preempts California's Proposition 65, to the extent that the state law mandates the placement of warnings on products containing nicotine sold over the counter as aids to stop smoking. The California Supreme Court concluded that an FDA letter "established a federal policy prohibiting defendants from giving consumers any warning other than the one approved by the FDA in that letter." *Id.* at 11. FDA's letter established a federal policy directed towards a "nuanced goal – to inform pregnant women of the risks of [Nicotine Replacement Therapy] products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking." *Id.* at 15. The court held that this federal policy "creates a conflict with the state's more single-minded goal of informing the consumer of the risks," and therefore held the state law preempted. *Id.*

In reaching that conclusion, the California Supreme Court expressly rejected plaintiff's argument that "the FDA action is not sufficiently definite and authoritative to create a conflict with state law." *Id.* at 9. The court held that, although FDA's letter "did not expressly reject all possible Proposition 65 warnings," it "announced . . . that the FDA had developed 'a uniform warning that manufacturers . . . will be requested to implement.'" *Id.* at 10 (quoting FDA letter at 5). The court also rejected the plaintiff's argument that FDA's letter should not be considered authoritative because it "has not been published in the Federal Register." *Id.* The Court concluded: "There is no requirement . . .

that it be so published to be effective." *Id.* The California Supreme Court observed that this Court's decision in *Geier*, 529 U.S. at 883-84, rejected "a contention that formal notice-and-comment rulemaking should be required before an agency's action has preemptive force," and "found federal policy to be sufficiently definite as to create a conflict when that policy was set out only in comments of the Department of Transportation accompanying its revision of the airbag rules and in statements in the Solicitor General's brief submitted on the agency's behalf." *Dowhal*, 88 P.3d at 10.

In this case, the court of appeals acknowledged this Court's decisions holding that federal regulations, as well as federal statutes, can preempt state law. App., *infra*, 9a (citing *New York* v. *FCC*, 486 U.S. at 63). It also recognized that notice-and-comment rulemaking is not the only type of agency action that can preempt state law. *Id.* (citing *Colacicco*, 521 F.3d at 271); *see Geier*, 529 U.S. at 883-84. "It is clear, for example, that federal agency orders resulting from quasi-judicial agency proceedings may constitute 'federal law' under the Supremacy Clause." App., *infra*, 9a-10a (citations omitted). Such proceedings may establish a policy that is "applicable not only to the immediate participants but also to others in like circumstances, such as the defendants." *Id.* at 11a.

Yet the court of appeals held that neither FDA's letter nor its other regulatory actions concerning methylmercury in tuna is sufficient to "create federal law capable of preemption." App., *infra*, 13a. In *Dowhal*, in contrast, the California

Supreme Court held that an FDA letter *did* adopt a federal policy that preempted conflicting state law, and specifically rejected arguments that the letter was not sufficiently authoritative or definite to have preemptive effect.[6]

Although the court of appeals did not cite or discuss the California Supreme Court's decision in *Dowhal*, it stated that it had "found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new obligations on anyone was held to create federal law capable of preemption." App., *infra*, 13a. The California Supreme Court's opinion in *Dowhal* does not hold or even suggest that these were critical elements of its decision. Moreover, the FDA's letter denying the Martek Petition (which is quoted and discussed in FDA's letter to the California Attorney General) *was* the product of an agency proceeding, initiated by Martek's petition to require that any qualified health claims for omega-3 fatty acids be accompanied by a warning about the risks of mercury in fish. In denying that petition following public notice and an opportunity for comment, FDA expressly stated that it "has decided that it is preferable not to use a label statement about mercury." FDA Martek Petition Denial at 29.

The court of appeals nevertheless held that FDA has not made an "authoritative" agency

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[6] Indeed, the letter at issue in this case was signed by the head of FDA, while the letter at issue in *Dowhal* was signed by a subordinate FDA official.

determination that the issue of mercury in fish products shall be left unregulated. *Id.* at 15a (citing *Sprietsma*, 537 U.S. at 67). As in *Dowhal*, however, FDA's letter sets forth a considered determination that a warning concerning the risks of mercury in tuna should not be included on the product label. FDA did not simply conclude that it would not require such a label, but that the likely risks to health associated with such a warning outweigh the likely benefits. As in *Geier*, FDA "is likely to have a thorough understanding of its own [policy] and its objectives, and is 'uniquely qualified' to comprehend the likely impact of state requirements." 529 U.S. at 883. Moreover, there is "no reason to suspect" that the FDA letter—which sets out the agency's longstanding position that targeted consumer advisories on mercury in fish rather than a general warning on product labels is the regulatory approach that best serves public health—"reflects anything other than 'the agency's fair and considered judgment on the matter.'" *Id.* at 884 (quoting *Auer* v. *Robbins*, 519 U.S. 452, 461-62 (1997)). For these reasons, this case is unlike *Sprietsma*, in which the federal agency made a simple decision not to regulate that stopped short of an "authoritative message" of a federal policy against regulation. 537 U.S. at 67.

The court of appeals relied on language in this Court's opinion in *Sprietsma* that "although the Coast Guard's decision not to require propeller guards was undoubtedly intentional and carefully considered, it does not convey an 'authoritative' message of a federal policy against propeller guards." 537 U.S. at 67 (quoting *Arkansas Elec. Coop.* v.

Arkansas P.S.C., 461 U.S. 375, 384 (1983)). The Third Circuit interpreted this statement as requiring that the federal agency's decision must carry the force of law. App., *infra*, 16a. As explained above, FDA's decision to establish an authoritative policy against mercury warning labels, and its rejection of the Martek Petition following notice and an opportunity for comment, do carry the force of law. But even if that were not so, the Third Circuit's understanding of this Court's opinions is incorrect for several reasons.

First, the term "authoritative" in *Sprietsma* is quoted from the Court's opinion in *Arkansas Electric Coop.*, which stated: "[A] federal decision to forgo regulation in a given area may *imply* an authoritative federal determination that the area is best left unregulated, and in that event would have as much pre-emptive force as a decision to regulate." 461 U.S. at 384 (emphasis added; original emphasis deleted). Given that an authoritative federal determination may be conveyed by implication, it cannot be the case that *Arkansas Electric Co-op.* or *Sprietsma* requires that the agency's determination carry the force of law.

Second, the four-Justice minority in *Geier*, two years earlier, would have required the agency to subject its preemption determination to notice-and-comment rulemaking and publish its determination in the *Federal Register*. *Geier*, 529 U.S. at 911 (Stevens, J., dissenting). It is noteworthy that the Court's decision in *Sprietsma* mentions no such requirements. *Third*, as a practical matter, an

agency's decision *not* to regulate is rarely set forth in a regulation.[7]

Further review is warranted to resolve the conflict with *Dowhal* and to make clear that FDA's authoritative policy against product labels warning about mercury in fish is sufficiently formal to preempt conflicting state law.

II. The Court Of Appeals' Decision Allows Manufacturers To Be Held Liable For Failing To Include A Label Warning That Would Violate Federal Law.

The head of FDA has issued a written determination that adding warnings about the risks of methylmercury to the labels of tuna products would cause the products to be misbranded in violation of Section 403 of the FDCA. FDA determined that the warnings required by California's Proposition 65 would be misleading because they lack a "scientific basis as to the possible

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[7] The court of appeals did not address Respondent's argument—made for the first time on appeal—that the complaint asserts a "design defect" claim that is not preempted. App., *infra*, 3a n.1. Respondent contends that Petitioner's tuna is "unsafe to eat" because it contains methylmercury. Resp. C.A. Br. at 44. Petitioner disagrees that there is any viable "design defect" claim separate from Respondent's failure to warn claim; however, any such claim would be preempted by FDA's regulatory determination that fish with a mercury level of less than 1.0 part per million (like that sold by Petitioner) is safe for consumption, *see* 44 Fed. Reg. at 3,993 (Jan. 19, 1979), and by its considered regulatory decision that warning labels are inappropriate for mercury in tuna.

harm caused by the particular food in question, or as to the amounts of such foods that would be required to cause this harm," and "omit facts which are necessary to place the information in its proper context." FDA letter at 6. Accordingly, FDA determined that "[t]una manufacturers would not be able to comply both with Proposition 65 and the [FDCA]." *Id.*

The court of appeals recognized that "[h]ad the FDA considered the factual basis for the alleged duty to warn and exercised its misbranding authority to establish that a warning based on that data would be false and misleading under federal law—not merely that the FDA had failed to require the warning, but had exercised its authority specifically to reject it" then "a state failure-to-warn lawsuit would be preempted." App., *infra*, 33a-34a. Despite that recognition, the court of appeals concluded that FDA has expressed only an "informal policy opinion in a letter" that is not sufficient to give rise to preemption.

The Third Circuit's reasoning is flawed. As an initial matter, the prohibition on misbranding is imposed directly by the FDCA, not by FDA. Moreover, FDA has expressed more than an "informal . . . opinion" that adding warnings to the labels of tuna products would violate federal law. FDA's letter to the California Attorney General reflects a considered determination that including the warnings required by Proposition 65 on tuna labels would render the product misbranded in violation of the FDCA. In addition, FDA has rejected the Martek Petition, which asked the agency to

require that qualified health claims about fish be accompanied by warnings concerning methylmercury. In denying the Martek Petition, FDA found that product-label warnings are less effective than its advisories because they can confuse consumers and have adverse public health consequences. FDA Martek Petition Denial 28-29.

The court of appeals' decision places tuna manufacturers in a double-bind. If they add warnings about the risks of methylmercury to the labels of tuna products, they subject themselves to liability under federal law. But if they omit such warnings, they risk liability under state tort law. While the court of appeals asserted that "FDA has taken no misbranding action pertaining to the risk of mercury in tuna," App., *infra*, 34a, regulated parties are not permitted to wait for an engraved invitation to comply with federal law. Nor should they be required—on threat of civil damages—to comply with conflicting state obligations until they are directly ordered to do otherwise.[8]

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[8] The Court has recognized that judgments based on state common-law, as well as state statutes, create legal duties that are preempted if they conflict with federal law. *See Riegel* v. *Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) ("[C]ommon-law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation . . . . And while the common-law remedy is limited to damages, a liability award 'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'") (quoting *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992)).

The court of appeals' opinion is in significant conflict with the Second Circuit's decision in *Grocery Manufacturers of America, Inc.* v. *Gerace*, 755 F.2d 993 (2d Cir. 1985). In that case, the Second Circuit held that a New York law requiring that the word "imitation" be used in the labeling of certain cheese products "would render the product misbranded under federal law." *Id.* at 1001. Accordingly, "[c]ompliance with both the state and federal requirements is impossible," and therefore "[t]o the extent that it attempts to regulate the labeling of alternative cheese, the New York law is preempted." *Id.* Here, contrary to the Second Circuit in *Grocery Manufacturers*, the Third Circuit would permit a lawsuit imposing liability for a manufacturer's failure to include a label that FDA has concluded would render the product misbranded.

The court of appeals suggested that Petitioner could satisfy both federal and state requirements by including label warnings that only "frequent tuna consumption" might be harmful, while "moderate fish consumption offers positive health benefits." App., *infra*, 35a. But the court's simplistic formulation does not address FDA's misbranding concerns and fails to take account of the nuanced and detailed content of the FDA Advisory.

Just as with the Proposition 65 warnings addressed in the FDA letter, the vague warning suggested by the court of appeals would be added "without any scientific basis as to the possible harm caused by the particular foods in question, or as to the amounts of such foods that would be required to cause this harm." FDA letter at 6. Consequently,

the court of appeals' suggested warning would be "misleading under section 403 of the Act, causing tuna products with such warnings to be misbranded under federal law." *Id.*

Moreover, the court of appeals' suggested warning ignores the greater part of FDA's message: First, it fails to distinguish the targeted population, pregnant women, women who may become pregnant, nursing mothers, and young children, from other fish consumers. *See* 2004 Advisory, http://www.cfsan.fda.gov/~dms/admehg3.html. Second, it fails to state that women and young children are advised to eat up to 12 ounces (or two average meals) of fish that are low in mercury each week, including canned light tuna. *Id.* Third, it fails to state that, when choosing these two meals, women and children may eat up to 6 ounces per week of albacore tuna, which has more mercury than canned light tuna. *Id.* Fourth, it fails to advise consumers that if they eat fish that is locally caught by family or friends, they should eat only 6 ounces of fish per week. *Id.*

Most fundamentally, the Third Circuit ignored the conflict between a state-law warning requirement and FDA's determination that warnings concerning the risks of mercury in fish are better conveyed through consumer advisories and other means that are directed to the target subpopulation, because label warnings would discourage the general population from consuming fish, and thus have a negative effect on the public health. FDA letter at 6.

III. The Court of Appeals' Decision Conflicts With Other Courts On The Application Of A Presumption Against Preemption In Conflict Preemption Cases.

The court of appeals applied a presumption that Respondent's failure to warn claim is not preempted. App., *infra*, 18a-21a. The court acknowledged that this Court "has applied the presumption in few conflict preemption cases of late," and that "arguments have been raised that the conflict preemption analysis subsumes or supplants the presumption." App., *infra*, 21a (citing *Colacicco*, 521 F.3d at 265). The court nevertheless held that it "will continue to apply the traditional presumption until the Supreme Court provides guidance to the contrary." App., *infra*, 21a.

The court of appeals started from the proposition that such a presumption applies in "all pre-emption cases," including conflict preemption cases. App., *infra*, 18a-19a (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996)).[9] The court stated "that the presumption remains applicable when preemption claims concern areas of the law 'which

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[9] An "actual conflict" between State and Federal law exists "where it is impossible for a private party to comply with both state and federal requirements," or "where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). There is no "legal wedge" between, and thus "no grounds . . . for attempting to distinguish," these two manifestations of actual conflict. *Geier*, 529 U.S. at 873-74.

the States have traditionally occupied,' but that it may not be applicable 'where the interests at stake are uniquely federal in nature.'" *Id.* at 19a (quoting *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001)). The court concluded that "a state tort-like action seeking damages for an alleged failure to warn" fits "squarely within the realm of traditional state regulation." App., *infra*, 19a-20a.[10]

The court of appeals' application of a presumption against preemption is contrary to decisions of the Eleventh and Fifth Circuits and other courts that have held no presumption is appropriate in conflict preemption cases. The court of appeals' decision is also inconsistent with the practice of this Court, which generally has not applied a presumption in conflict preemption cases.

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[10] Several courts have followed this Court's holding in *Buckman* that no presumption against preemption applies when the subject of the lawsuit involves an area that has not traditionally been regulated by the States. *E.g.*, *Forest Park II* v. *Hadley*, 336 F.3d 724, 731 (8th Cir. 2003) ("[U]nlike cases involving a field traditionally regulated by the states, there is no presumption against preemption in this case."); *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199, 1205 (9th Cir. 2002) (no presumption against preemption for fraud on FDA claim). Given the long history of federal standards for food safety, Petitioner disagrees that Respondent's failure to warn claim involves an area traditionally regulated by the states. In applying a presumption against preemption here, the Third Circuit failed to recognize that an assertion of conflict preemption is a separate reason to proceed without any such presumption.

A. The Court Of Appeals' Decision Conflicts With Decisions Of Other Circuits.

In *Irving* v. *Mazda Motor Corp.*, 136 F.3d 764 (11th Cir. 1998), the Eleventh Circuit considered whether a claim that a seatbelt was defectively designed was expressly or impliedly preempted by the a Federal Motor Vehicle Safety Standard. The court held that while there is a "'strong presumption'" against preemption in express preemption cases, "[w]hen considering implied preemption, no presumption exists against preemption." *Id.* at 767 (quoting *Taylor* v. *Gen. Motors Corp.*, 875 F.2d 816, 823 (11th Cir. 1989)), 769. The Eleventh Circuit rejected the argument that an anti-preemption presumption should apply in conflict cases that involve an area of state concern: "'Under the Supremacy Clause of the Federal constitution, the relative importance to the State of its own law is not material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'" *Id.* at 769 (quoting *Lewis* v. *Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997)).

The Eleventh Circuit recently confirmed that it does not apply a presumption against preemption in conflict cases: "[I]n practice it is difficult to understand what a presumption in conflict preemption cases amounts to, as we are surely not requiring Congress to state expressly that a given state law is preempted using some formula or magic words." *Florida State Conference of the NAACP* v. *Browning*, 522 F.3d 1153, 1168 (11th Cir. 2008),

(citing *Irving*, 136 F.3d at 769). "Either Congress intended to displace certain state laws or it did not. Federal law is not obliged to bend over backwards to accommodate contradictory state laws, as should be clear from the Supremacy Clause's blanket instruction . . . ." *Id.* The court concluded that it "will not apply a presumption to give less preemptive effect than Congress intended," nor "apply an overly broad construction . . . to give more than Congress intended." *Id.*

The Fifth Circuit has similarly held that, in contrast to *express* preemption cases, "we do not begin with an assumption against *conflict* preemption." *Perry* v. *Mercedes Benz of N. Am., Inc.*, 957 F.2d 1257, 1261-1262 (5th Cir. 1992) (emphasis in original). The Fifth Circuit agrees with the Eleventh Circuit that "'[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'" *Id.* (quoting *Felder* v. *Casey*, 487 U.S. 131, 138 (1988)).[11]

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[11] Lower federal and state courts have similarly declined to apply a presumption against preemption in conflict cases. *See, e.g.*, *Masterson* v. *Apotex, Corp.*, 2008 U.S. Dist. LEXIS 60238, *7-*8 (S.D. Fla. Aug. 7, 2008) ("[T]he presumption against preemption is inapplicable in the context of implied conflict preemption."); *Gentry* v. *Volkswagen of Am., Inc.*, 521 S.E.2d 13, 16 (Ga. App. 1999) ("'[W]hen considering implied preemption, no presumption exists against preemption.'" (quoting *Irving*, 136 F.3d at 769)).

The Third Circuit's application of a presumption against preemption here is directly contrary to the decisions of the Fifth and Eleventh Circuits. By suing under the theory that Petitioner should have included a warning about the risks of methylmercury in tuna, Respondent's tort action conflicts with the nuanced federal policy against food warnings in general, and with FDA's specific policy against warnings for mercury in tuna. The Third Circuit presumed that the action is not preempted, while the Fifth and Eleventh Circuits would not have proceeded from such a presumption.

B. A Presumption Against Preemption In Conflict Cases Is Contrary To This Court's Recent Practice.

While this Court has at times applied a presumption against preemption in express preemption[12] and field preemption cases,[13] the Court's conflict preemption cases, almost without exception, do not apply any presumption against preemption. *See, e.g.*, *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002); *Geier*, 529 U.S. 861; *United States* v. *Locke*, 529 U.S. 89 (2000); *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000);

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[12] *See, e.g.*, *Bates* v. *Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005); *Lohr*, 518 U.S. at 485; *Cipollone*, 505 U.S. at 518.

[13] *English*, 496 U.S. at 79; *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985); *but see Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 247 (1984) (no mention of presumption in field preemption analysis).

Freightliner Corp. v. *Myrick*, 514 U.S. 280 (1995); *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) (plurality op.); *La. Pub. Serv. Comm'n* v. *FCC*, 476 U.S. 355 (1986); *Wis. Dep't of Indus., Labor & Human Relations* v. *Gould, Inc.*, 475 U.S. 282 (1986); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202 (1985); *Brown* v. *Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491 (1984); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691 (1984).[14]

The Court's decisions in conflict cases have most often emphasized ordinary principles of statutory construction without applying any presumption in favor of or against preemption. For example, in *Geier*, the majority did not mention the presumption against preemption. *See* 529 U.S. at 906-907 (Stevens, J., dissenting) ("the Court simply ignores the presumption [against preemption], preferring instead to put the burden on petitioners to show that their tort claim would not frustrate [federal] purposes"). Instead, the Court relied on "longstanding," "ordinary," and "experience-proved

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[14] While the Court mentioned the presumption in two conflict preemption cases, *California* v. *ARC America Corp.*, 490 U.S. 93, 101 (1989), and *Hillsborough County*, it did not rely on the presumption in its conflict preemption analysis in either case. *ARC*, 490 U.S. at 105-106; *Hillsborough County*, 471 U.S. at 722. Similarly, in two cases that involved claims of both conflict and field preemption, the Court invoked the presumption only in the field preemption analysis and not in the conflict preemption analysis. *See Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 491 (1987); *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977).

principles of conflict pre-emption." *Geier*, 529 U.S. at 874.

Other recent cases are consistent with *Geier*. In *United States* v. *Locke*, the Court described the presumption as "artificial," declining to invoke it in analyzing whether federal law conflicted with state regulations in "an area where there has been a history of significant federal presence." 529 U.S. 89, 108 (2000). And in *Sprietsma*, the Court did not mention the presumption in its holding that there was no conflict between the Coast Guard's decision not to require propeller guards on boat motors and a purported state tort-law duty to install such guards. 537 U.S. at 64-68. The Court has also recognized that the applicability of the presumption in a conflict preemption case remains an open question. *Crosby*, 530 U.S. at 374 n.8 ("We leave for another day a consideration in this context of a presumption against preemption.").

In *Altria Group, Inc.* v. *Good*, the Court stated that its analysis in "express or implied preemption" questions began with an "'assumption'" that States' "historic police powers" are not preempted "'unless that was the clear and manifest purpose of Congress.'" 129 S.Ct. 538, 543 (2008), (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). But the Court went on to address the presumption only with regard to express preemption, concluding that "[w]hen the *text of a pre-emption clause* is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'" *Id.* at 540 (emphasis added) (quoting *Bates*, 544 U.S. at 449). The Court did not mention

the presumption in its discussion of the conflict preemption question in *Altria Group*. *See id.* at 549-51.[15]

As the Eleventh and Fifth Circuits have held, a presumption against preemption makes little sense in conflict preemption cases. The presumption originated in a field preemption case, with the Court stating that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230 (citations omitted). Following *Rice*, in its express preemption cases the Court has applied the presumption as a principle of statutory construction favoring a narrow reading. *Lohr*, 510 U.S. at 485 (the presumption supports "a narrow interpretation of such an express command") (plurality op.); *Cipollone*, 505 U.S. at 518 ("This presumption reinforces the appropriateness of a narrow reading."). But when the issue is whether a state law conflicts with federal law, either because it is impossible to comply with both, or because the state law stands as an obstacle to the accomplishment of the federal law, there is no occasion to make any presumption about congressional intent: Congress intends that its laws will be fully effective, and the Supremacy Clause

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[15] Unlike *Altria Group*, where the government argued that there was no policy that preempted the state cause of action, here FDA's letter concludes that it would be impossible to comply with both FDA's regulatory requirements and state law requiring a warning on the product label concerning methylmercury in fish. *See supra*, pp 23-27.

ensures that "any Thing" to the contrary in State law must yield. As the Court noted in *Geier*:

> Why, in any event, would Congress not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake? Some such principle is needed. In its absence, state law could impose legal duties that would conflict directly with federal regulatory mandates.

529 U.S. at 871. The courts should thus focus on the existence of a conflict between the state and federal law without any presumption that the federal law should be read narrowly not to interfere with the state law.

In the light of this Court's decisions and the disagreement in the courts of appeals over whether the presumption against preemption applies to conflict preemption questions, certiorari should be granted to clarify that no presumption is appropriate in conflict preemption cases.

CONCLUSION

The petition for a writ of certiorari should be granted.[16]

Respectfully submitted,

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January 2009

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[16] This Court heard oral argument in *Wyeth* v. *Levine*, Docket No. 06-1249, on November 3, 2008. *Wyeth* presents the question whether prescription drug labeling judgments made by FDA pursuant to the FDCA preempt state-law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use. *See* Pet. Br. in No. 06-1249, at i. Because of the similarities between this case and *Wyeth*, the Court may wish to hold the petition in this case pending its decision in *Wyeth*, and then dispose of the petition as appropriate in the light of the Court's decision in that case.

APPENDIX

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 07-1238

DEBORAH FELLNER, individually and on behalf of those similarly situated

v.

TRI-UNION SEAFOODS, L.L.C.
d/b/a CHICKEN OF THE SEA,

Deborah Fellner,
Appellant

On Appeal From the United States District Court
For the District of New Jersey
(D.C. Civil Action No. 06-cv-00688)
District Judge: Hon. Dennis M. Cavanaugh

Argued February 12, 2008

BEFORE: SLOVITER, SMITH and STAPLETON,
Circuit Judges

(Opinion filed: August 19, 2008)

OPINION OF THE COURT

STAPLETON , Circuit Judge:

Plaintiff Deborah Fellner filed this lawsuit against defendant Tri-Union Seafoods, LLC ("Tri-Union") in the Superior Court of New Jersey seeking damages for harm she allegedly sustained as a result of her consumption of methylmercury and other harmful compounds contained in Tri-Union's tuna fish products. The case was removed to federal court, and Tri-Union filed a motion to dismiss for failure to state a claim asserting that Fellner's lawsuit is preempted by regulatory actions of the United States Food and Drug Administration ("FDA"). The District Court granted the motion, ruling that Fellner's claims are preempted by the FDA's "regulatory approach" to the risks posed by mercury compounds in tuna fish. Because we conclude that the FDA has taken no regulatory action which preempts Fellner's lawsuit, we will reverse and remand for further proceedings.

I. Facts and Procedural Background

Fellner alleges that Tri-Union produces, cans and distributes Chicken-of-the-Sea brand tuna fish and that, from 1999 to 2004, her diet consisted almost exclusively of TriUnion's tuna products. She further avers that those products contained methylmercury and other harmful compounds that can result in mercury poisoning and that "[d]ue to the negligence and statutory violations of the Defendant . . . Fellner contracted severe mercury poisoning and suffered extreme physical and emotional injuries." App. at 30a, P 28. She seeks recovery under the New Jersey Products Liability

Act, N.J.S.A. 2A:58C-1, et seq. ("NJPLA"), based on Tri-Union's failure to warn of the risks incurred in consuming its products.[1]

The factual landscape of this case is colored by recent litigation in California. On June 21, 2004, then-Attorney General of California, Bill Lockyer, filed a lawsuit against Tri-Union and other defendants under California's "Proposition 65," CAL. HEALTH & SAFETY CODE § 25249.6, seeking an injunction and civil penalties for defendants' failure to warn consumers that their tuna products contain dangerous mercury compounds. While that suit was pending, the Commissioner of the FDA sent a letter to Mr. Lockyer expressing the opinion that the FDA's prior regulatory actions preempt the State's lawsuit. In the Commissioner's view, the defendants would be unable to comply both with that approach and state law and the existence of the lawsuit would "frustrate the [FDA's] carefully considered federal approach" to the issue of mercury in fish. *See People* v. *Tri-Union Seafoods*, 2006 WL 1544377 (Cal. Super. Ct. May 12, 2006) (taking judicial notice of the letter). In May

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[1] While the complaint refers to a design defect, we find it unclear whether the alleged design defect is the failure to warn or is a claim based on excessive mercury concentrations which is distinct from the failure to warn. The District Court apparently reached the former conclusion; it dismissed the failure-to-warn claim without addressing whether the complaint asserts a separate design-defect claim and whether any such claim is preempted. Due to this posture, and because our disposition of this appeal will result in remand to the District Court, we decline to address the design defect claim, if one there be, and instead will allow the parties to raise these issues before the District Court if they so choose.

2006, following a bench trial, the Superior Court of California found the Attorney General's lawsuit preempted by federal law. *People* v. *Tri-Union Seafoods*, 2006 WL 1544384 (Cal. Super. Ct. May 11, 2006), appeal docketed, No. A116792 (Cal. Ct. App. 1st Dist. Feb. 20, 2007).

Tri-Union removed Fellner's lawsuit to the United States District Court for the District of New Jersey and filed a motion to dismiss for failure to state a claim accompanied by motions requesting that the Court take judicial notice of four documents: (1) a consumer advisory published by the FDA in 2004 regarding the risks of mercury in fish ("the Advisory"); (2) a "backgrounder" for the FDA's 2004 Advisory, which provides further information about those risks ("the backgrounder"); (3) Section 504.0600 of the FDA's Compliance Policy Guide, a guideline recommending that the FDA initiate enforcement action if the concentration of mercury in fish exceeds "1 ppm" ("the Compliance Guide"); and (4) the above-described letter sent by the Commissioner of the FDA to the Attorney General of California ("the Commissioner's letter").

The District Court took judicial notice of the four documents submitted by defendant and granted defendant's motion to dismiss. *Fellner* v. *Tri-Union Seafoods*, 2007 U.S. Dist. LEXIS 1623, 2007 WL 87633 (D.N.J. 2007). It found that the FDA had implemented a "pervasive regulatory scheme" pertaining to the risks of methylmercury in fish consisting of the FDA's Advisory, backgrounder, Compliance Guide, and the Commissioner's letter. It concluded that the FDA had deliberately declined to require warnings in favor of a more "nuanced" and

"balanced" approach consisting of targeted advisories, and that the state law duties relied upon by Fellner in her lawsuit would upset that approach. As a result, the Court dismissed the complaint, holding that the FDA's regulatory scheme regarding mercury in fish preempts Fellner's state law claims. She timely appealed.

II. Jurisdiction and Standard of Review

We have jurisdiction pursuant to 28 U.S.C. § 1291. We exercise plenary review of the District Court's order granting defendant's motion to dismiss. *Santiago* v. *GMAC Mortg. Group, Inc.*, 417 F.3d 384, 386 (3d Cir. 2005). When reviewing a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), we accept as true all well-pled factual allegations in the complaint and all reasonable inferences that can be drawn from them, and we affirm the order of dismissal only if the pleading does not plausibly suggest an entitlement to relief. *Wilkerson* v. *New Media Tech. Charter Sch.*, 522 F.3d 315, 321- 22 (3d Cir. 2008).

III. Discussion

The sole question presented in this appeal is whether Fellner's state claim for damages is preempted by federal law. Tri-Union offers three distinct theories of preemption: (1) that the FDA has adopted a "pervasive regulatory approach" -- embodied in the FDA's Advisory, backgrounder and internal enforcement guideline -- with which Fellner's state lawsuit actually conflicts; (2) that the FDA has "reject[ed] the use of warning labels" in favor of a more "nuanced" approach -- that is, that the FDA has reached a decision that warnings

should not be regulated, a decision which preempts the state from entertaining a claim based on a duty to warn theory; and (3) that the FDA would have rejected any warning as "misbranding," a determination which preempts Fellner's failure-to-warn claim.

A. The Doctrine of Federal Preemption

The doctrine of federal preemption is rooted in the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2, which invalidates state laws that "interfere with, or are contrary to, federal law." *Hillsborough County* v. *Automated Med. Labs.*, 471 U.S. 707, 712, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985) (quoting *Gibbons* v. *Ogden*, 22 U.S. 1 (9 Wheat. 1, 211, 6 L. Ed. 23), (1824)). As we recently explained,

> [t]he Supreme Court has identified three major situations where there is preemption . . . (1) "express" preemption, applicable when Congress expressly states its intent to preempt state law; (2) "field" preemption, applicable when "Congress' intent to pre-empt all state law in a particular area may be inferred [because] the scheme of federal regulation is sufficiently comprehensive" or "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject;" and (3) "conflict" preemption, applicable when "state law is nullified to the extent that it actually conflicts with federal law," even though

> Congress has not displaced all state law in a given area.

Colacicco v. *Apotex Inc.*, 521 F.3d 253, 261 (3d Cir. 2008) (quoting Hillsborough County, 471 U.S. at 713). *See also English* v. *General Elec. Co.*, 496 U.S. 72, 78-79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990) (summarizing the three types of preemption). Tri-Union has not argued, nor could it, that Fellner's lawsuit is expressly preempted by the Food, Drug and Cosmetics Act ("FDCA") or by federal regulation.[2] Similarly, we do not interpret TriUnion's brief as asserting a field preemption claim, and any such claim would be unavailing.[3] If preemption exists in this case it must be conflict preemption.

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[2] The Act includes an express preemption provision, 21 U.S.C. § 343-1, but Tri-Union does not urge that it governs this case. The inclusion of express preemption provisions does not preclude the operation of ordinary implied preemption principles. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000).

[3] Courts rarely find field preemption, especially in areas traditionally regulated by the states, unless the structure of a regulatory program leaves little doubt that Congress intended federal law to be exclusive in a particular field. *See, e.g.*, Hillsborough County, 471 U.S. at 717 ("merely because the federal provisions [are] sufficiently comprehensive to meet the need identified by Congress [does] not mean that States and localities [are] barred from identifying additional needs or imposing further requirements in the field . . . . We are even more reluctant to infer preemption from the comprehensiveness of regulations than from the comprehensiveness of statutes . . ."). In this case, the "regulatory scheme" identified by TriUnion and the Commissioner's letter fall far short of the sort of comprehensive federal program ordinarily addressed in field preemption cases.

As the Supreme Court frequently reiterates, in all cases "preemption fundamentally is a question of congressional intent." *English*, 496 U.S. at 78-79. *See also Medtronic* v. *Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) ("'[t]he purpose of Congress is the ultimate touchstone' in every preemption case") (citation omitted). However, "state laws can be preempted by federal regulations as well as by federal statutes." *Hillsborough County*, 471 U.S. at 713. Where Congress has delegated the authority to regulate a particular field to an administrative agency, the agency's regulations issued pursuant to that authority have no less preemptive effect than federal statutes, assuming those regulations are a valid exercise of the agency's delegated authority. *Fidelity Fed. Savings and Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153-54, 102 S. Ct. 3014, 73 L. Ed. 2d 664 (1982).

Although federal administrative law as well as Congressional enactments are the supreme law of the land, we must reiterate, lest the analysis become unmoored, that it is federal law which preempts contrary state law; nothing short of federal law can have that effect. The Supreme Court's longstanding interpretation of the Supremacy Clause, and indeed the Supremacy Clause itself, mandate this principle:

> Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any states to the Contrary notwithstanding." Art. VI, cl.2. Thus, since our decision in *M'culloch* v. *Maryland*, it has been settled that state

> law that conflicts with federal law is "without effect."

Cipollone, 505 U.S. at 516 (emphasis added). *See also Colacicco*, 521 F.3d at 261 ("[e]arly in our constitutional history, the Supreme Court interpreted this language to invalidate state laws that 'interfere with, or are contrary to,' federal law, the genesis of the preemption doctrine") (emphasis added; citation omitted).

As we have noted, there is no doubt that federal regulations as well as statutes can establish federal law having preemptive force. *New York* v. *Fed. Commc'n Comm'n*, 486 U.S. 57, 63, 108 S. Ct. 1637, 100 L. Ed. 2d 48 (1988) ("The phrase 'Laws of the United States' [in the Supremacy Clause] encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization"). Although there is some authority for the proposition that the only regulatory process which can produce "federal law" for purposes of the Supremacy Clause is formal, notice and comment rulemaking, *Good* v. *Altria Group*, 501 F.3d 29, 51-52 (1st Cir. 2007), cert. granted, 128 S. Ct. 1119, 169 L. Ed. 2d 846 (2008) (collecting cases), we have joined those courts which hold that, in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal, notice and comment rulemaking may also have preemptive effect over state law. *Colacicco*, 521 F.3d at 271 (citations omitted).

It is clear, for example, that federal agency orders resulting from quasi-judicial agency proceedings may constitute "federal law" under the

Supremacy Clause: "[i]t is well established that when developing law on a subject, an agency usually has a choice between the method of rulemaking and that of adjudication," *General Motors Corp.* v. *Abrams*, 897 F.2d 34, 39 (2d Cir. 1990) (citation omitted); both agencies' quasi-legislative as well as their quasi-judicial powers "have the binding force of 'federal law.'" *Id.* (citation omitted). *See also Chicago and Nw. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 314-15, 321-28, 101 S. Ct. 1124, 67 L. Ed. 2d 258 (1981) (Interstate Commerce Commission order following quasi-judicial proceeding governing abandonment of rail lines preempted state law). Moreover, in addition to orders from formal adjudicatory proceedings, we have recently given preemptive effect to a federal agency order in a similar situation where a comprehensive federal regulatory scheme authorized a process for the agency to apply a federal standard to concrete circumstances, and it had utilized that process in a manner establishing a federal duty or policy. In *Colacicco*, the plaintiffs' alleged claims for failure to warn that a family of drugs used to treat anxiety and depression caused an increased risk of suicidality. The FDCA conferred jurisdiction upon the FDA to regulate drug labeling. Regulations authorized by the FDCA predicated the marketing of drugs on FDA approval of the drugs' labeling both at the time the drugs were initially marketed and on an ongoing basis thereafter. Defendants' labels had received FDA approval both before and after the suicides at issue. The plaintiffs pointed out, however, that the regulations required that the labeling be revised by the manufacturer unilaterally "to include a warning as soon as there is reasonable evidence of an

association of a serious hazard with a drug." 21 C.F.R. § 201.57(c) (2003). Plaintiffs argued that this meant the defendants could have complied with both the federal regulations and the state duty to warn, and thus no conflict existed. We rejected this argument because, although the regulations allowed a manufacturer to amend warnings unilaterally, all such amendments remained contingent on the manufacturer ultimately receiving FDA approval, and the FDA in a number of different agency proceedings had previously considered the scientific evidence relied upon by plaintiffs and had exercised its prerogative under the regulations to reject suicidality warnings based on that evidence. The FDA had "clearly and publicly stated its position [regarding the propriety of the warning in the pertinent circumstances] prior to the prescriptions and deaths at issue. . . ." *Colacicco*, 521 F.3d at 271. Although defendants had not been shown to be participants in those proceedings, we concluded that a conflict existed because, much like agency quasi-judicial proceedings, *see Security and Exchange Commission* v. *Chenery Corp.*, 332 U.S. 194, 201-03, 67 S. Ct. 1575, 91 L. Ed. 1995 (1947), the FDA's actions in those proceedings established a policy against the sought-after warnings applicable not only to the immediate participants but also to others in like circumstances, such as the defendants. Thus, defendants could not have complied with the requirements of both federal and state law.

This does not mean, however, that federal law capable of preempting state law is created every time someone acting on behalf of an agency makes a statement or takes an action within the agency's

jurisdiction. As the Supreme Court has explained, "[i]t is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *United States* v. *Mead Corp.*, 533 U.S. 218, 230, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001) (addressing which types of agency actions should be afforded Chevron deference). We believe that similar considerations are pertinent here. We decline to afford preemptive effect to less formal measures lacking the "fairness and deliberation" which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law. Courts with good reason are wary of affording preemptive force to actions taken under more informal circumstances. *See, e.g.*, *Good*, 501 F.3d at 51-52; *Wabash Valley Power Ass'n* v. *Rural Electrification Admin.*, 903 F.2d 445, 453-54 (7th Cir. 1990); *General Motors Corp.*, 897 F.2d at 39. Regularity of procedure -- whether it be the rulemaking and adjudicatory procedures of the APA or others which Congress may provide for a particular purpose -- not only ensures that state law will be preempted only by federal "law," as the Supremacy Clause provides, but also imposes a degree of accountability on decisions which will have the profound effect of displacing state laws, and affords some protection to the states that will have their laws displaced and to citizens who may hold rights or expectations under those laws.

Tri-Union points to the Commissioner's letter as both establishing federal law capable of

preemption and as evidencing the agency's interpretation of previously established law, an interpretation to which we should defer. We evaluate below the deference to which we believe that letter is entitled as an interpretation of pre-existing federal law. With respect to Tri-Union's claim that it established federal law, we note that we have found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption. *See Wabash Valley*, 903 F.2d at 453-54 (declining to give preemptive effect to an agency letter where the prescribed procedures were not followed); *Thomas* v. *New York*, 256 U.S. App. D.C. 49, 802 F.2d 1443 (D.C. Cir. 1986) (same).[4]

Finally, the Supreme Court occasionally has confronted a claim that a federal agency's decision not to regulate should be granted preemptive effect because it constitutes a federal determination that the issue shall be unregulated -- here, the decision not to require (or otherwise regulate) mercury warnings. As the Court explained, "a federal

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[4] Contrary to Tri-Union's suggestion, we do not read *Geier* as indicating otherwise. Although *Geier* declined to require a "specific, formal agency statement identifying a conflict in order to conclude that [] a conflict in fact exists," *Geier*, 529 U.S. at 884, it did require that state law actually conflict with a federal law. The Court ruled that a state lawsuit was preempted because it actually conflicted with a Department of Transportation ("DOT") regulation (FMVSS 208), id. at 874, and the Court merely "place[d] some weight upon the DOT's [informal] interpretation of FMVSS 208's objectives . . .," *id.* at 883, to help it determine whether the two in fact conflicted.

decision to forego regulation in a given area may imply an authoritative federal determination that the area is best left *un*regulated, and in that event would have as much preemptive force as a decision to regulate." *Ark. Elec. Co-op* v. *Ark. Pub. Serv.*, 461 U.S. 375, 384, 103 S. Ct. 1905, 76 L. Ed. 2d 1 (1983) (emphasis in original).

However, the Supreme Court has since cautioned that this statement in Arkansas Electric Co-op "was obviously not meant in an unqualified sense; otherwise, deliberate federal inaction could always imply preemption, which cannot be. There is no federal preemption in vacuo, without a constitutional text or a federal statute to assert it." *P.R. Dep't of Consumer Affairs* v. *Isla Petroleum Corp.*, 485 U.S. 495, 503, 108 S. Ct. 1350, 99 L. Ed. 2d 582 (1988). The Court further explained,

> [w]e are presented with the decidedly untypical claim that federal pre-emption exists despite not only the absence of a statutory provision specifically announcing it, but the absence of any extant federal regulatory program with which the state regulation might conflict and which might therefore be thought to imply pre-emption."

Id. at 500. The Court rejected the claim, concluding that "unenacted approvals, beliefs, and desires are not laws. Without a text that can, in light of those statements, plausibly be interpreted as prescribing federal pre-emption it is impossible to find that a free market was mandated by federal law." *Id.* at 501 (emphasis in original).

The Court again confronted, and rejected, a similar claim just a few years ago. Although the Court acknowledged that the agency had the authority to enact a regime free of any regulation concerning the risk at issue, it declined to infer such a regime from a mere decision not to regulate, absent an "'authoritative' message of a federal policy against [regulation]." *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 67, 123 S. Ct. 518, 154 L. Ed. 2d 466 (2002). The Court explained,

> [i]t is quite wrong to view [the Coast Guard's decision not to adopt a regulation] as the functional equivalent of a regulation prohibiting all States and their political subdivisions from adopting such a regulation . . . . Of course, if a state common-law claim directly conflicted with a federal regulation promulgated under the Act, or if it were impossible to comply with any such regulation without incurring liability under state common law, pre-emption would occur. This, however, is not such a case.

Sprietsma, 537 U.S. at 65 (emphasis added).[5]

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[5] *Sprietsma* discussed the agency's informal, contemporaneous explanation for its decision not to regulate and also emphasized that the agency had taken an anti-preemption position in briefings for the Court. *Sprietsma*, 537 U.S. at 67- 68. We do not interpret *Sprietsma* to have implied that, had the agency adopted a pro-preemption stance in an informal statement or briefings for the Court, those views alone would have imbued the agency's decision not to regulate with preemptive force. (...continued)

Isla Petroleum and *Sprietsma* make clear that mere deliberate agency inaction -- an agency decision not to regulate an issue -- will not alone preempt state law. Furthermore, we find no support for the proposition that an agency's informal explanation for its decision not to regulate can alone imbue such a decision with preemptive force; in all cases concerning alleged "federal determination[s] that [an] area is best left unregulated," *Ark. Elec. Co-op*, 461 U.S. at 384, the Supreme Court and Courts of Appeals have inquired whether some extant law or regulation evinced an "authoritative message of federal policy" that an issue is to remain free of state regulation (or any regulation at all); "unenacted approvals, beliefs, and desires" will not suffice.[6]

Geier directs that courts should consider any views expressed by the agency regarding the purposes and objectives of its actions claimed to preempt state law, and therefore it was only natural for *Sprietsma* to note the agency's agreement. Furthermore, *Sprietsma* emphasized a "stark contrast" with *Geier*: unlike the case before it, in *Geier* it was not mere inaction or a "decision not to regulate" combined with informal agency views that preempted state law but rather a federal regulation (FMVSS 208) that promulgated the "affirmative policy judgment" -- the "authoritative message of a federal policy" -- with which the state lawsuit was found to conflict. *Id.* at 68 (internal quotation marks and citation omitted).

[6] We find only two situations in which courts have given preemptive effect to decisions not to regulate. First, the Supreme Court has found deliberate federal inaction to preempt state law (so-called "negative preemption") through what is essentially a field preemption analysis: "[w]here a comprehensive federal scheme intentionally leaves a portion of the regulated field without controls, then the preemptive inference can be drawn -- not from federal inaction alone, but from inaction joined with action." *Isla Petroleum Corp.*, 485 (...continued)

U.S. at 503 (emphasis in original). In such cases, courts have concluded from the comprehensiveness of a statutory scheme and their interpretation of the purposes and objectives of the statute that Congress intended federal jurisdiction to be exclusive or the field to be free of any regulation whatsoever. *See, e.g., Ark. Elec. Co-op*, 461 U.S. at 384 (citing field preemption case for the proposition that a federal decision to forego regulation may imply an "authoritative federal determination that the area is best left unregulated;" finding no such determination); *Transcontinental Gas Pipe Line* v. *State Oil and Gas Bd.*, 474 U.S. 409, 422, 425, 106 S. Ct. 709, 88 L. Ed. 2d 732 (1986) (finding this brand of field preemption); *Bldg. & Constr. Trades Council* v. *Associated Builders & Contractors*, 507 U.S. 218, 224-27, 113 S. Ct. 1190, 122 L. Ed. 2d 565 (1993) (discussing two lines of such field preemption cases under the NLRA). *Cf. Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151, 178, 98 S. Ct. 988, 55 L. Ed. 2d 179 (1978) (agency's decision not to adopt a particular regulation contributed to a finding of conflict preemption where the agency took the subsequent step of adopting an alternate federal standard governing the issue with which, the Court found, the state rule would be inconsistent).

Second, other such cases appear to be simply express preemption cases -- Congress and federal agencies possessing the appropriate authority certainly may announce by law or regulation a federal policy that an issue is to remain unregulated. *See, e.g., Ark. Elec. Co-op*, 461 U.S. at 388-89 (stating that the federal agency could have announced a policy "that the area is best left unregulated" in a "rule [] valid under the [Act]" but had not done so); *Wabash Valley Power Ass'n*, 903 F.2d at 453-54 (discussing *Ark. Elec. Co-op*); *Gracia* v. *Volvo Europa Truck*, 112 F.3d 291, 296-97 (7th Cir. 1997), *cert. denied*, 522 U.S. 1050, 118 S. Ct. 697, 139 L. Ed. 2d 641 (1998) (explaining that, in contrast to cases where an agency simply declined to regulate an issue, "here there is a specific federal standard . . . [which] determined that this type of vehicle should be exempt from the affixing requirement . . ."); *Lynnbrook Farms* v. *Smithkline Beecham Corp.*, 79 F.3d 620, 625 (7th Cir. 1996), *cert. denied*, 519 U.S. 867, 117 S. Ct. 178, 136 L. Ed. 2d 118 (1996) (agency "declaration" of preemption issued in a formal rule); *Evans* v. *Bd. of County Comm'rs*, 994 F.2d 755, (...continued)

B. Presumption Against Preemption and Deference to the Agency

The parties dispute the applicability of two familiar rules of interpretation. Fellner asserts that we should apply a presumption against preemption. Tri-Union asserts that Fellner's reliance on the presumption against preemption is misplaced, and that in fact we should afford deference to the agency's views on preemption.

1. Presumption Against Preemption

The Supreme Court historically has applied a presumption against the preemption of state laws:

> because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," we "start with the assumption that the historic police powers of the States were not superseded by the Federal Act

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758-60 (10th Cir. 1993) (agency issued a "limited preemption policy" via a "Memorandum Opinion and Order" following notice and comment); *Ray*, 435 U.S. 171-72 (stating that the federal agency could promulgate "rules" announcing that it desired no regulation of an issue but had not done so); *Baltimore & O. R. Co.* v. *Oberly*, 837 F.2d 108, 115-16 and n. 3 (3d Cir. 1988) (citing *Ray*, 435 U.S. at 172-73 & n. 23, and other cases for the same proposition).

> unless that was the clear and manifest purpose of Congress."

Medtronic v. *Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (citations omitted). *See also Hillsborough County* v. *Automated Med. Labs.*, 471 U.S. 707, 715, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985) ("[w]here . . . the field that Congress is said to have pre-empted has been traditionally occupied by the States 'we start with the [presumption];'") (citation omitted); *Bates*, 544 U.S. at 449 (similar).

Recent Supreme Court jurisprudence suggests that the presumption remains applicable when preemption claims concern areas of the law "which the States have traditionally occupied," but that it may not be applicable "where the interests at stake are 'uniquely federal' in nature." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001) (declining to apply the presumption because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied' . . . . To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character") (citations omitted). *See also United States* v. *Locke*, 529 U.S. 89, 108, 120 S. Ct. 1135, 146 L. Ed. 2d 69 (2000) (presumption applies "in field[s] which the states have traditionally occupied," but declining to apply it because "national and international maritime commerce" is not such a field) (citations omitted).

In the present case, it is hard to imagine a field more squarely within the realm of traditional state regulation than a state tort-like action seeking

damages for an alleged failure to warn consumers of dangers arising from the use of a product. *See, e.g.*, *Bates*, 544 U.S. at 449 ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption"). Furthermore, state tort law and other similar state remedial actions are often deemed complementary to federal regulatory regimes, and this appears to be such a case. Federal regulatory programs frequently do not include a compensatory apparatus, and the Supreme Court has recognized that state tort law can also play an important information-gathering role not easily replicated by federal agencies.[7] When a litigant

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[7] *See, e.g.*, *Sprietsma*, 537 U.S. at 64 ("It would have been perfectly rational for Congress not to pre-empt common-law claims, which -- unlike most administrative and legislative regulations -- necessarily perform an important remedial role in compensating accident victims."); *Bates*, 544 U.S. at 449, 451 ("[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA . . . . FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings . . . tort suits can serve as a catalyst in this process;" concluding that "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly"); *Medtronic*, 518 U.S. at 487 (plurality opinion) ("because there is no explicit private cause of action [in the federal Act] . . . [a finding of preemption would mean] Congress would have barred most, if not all, relief for persons injured by defective medical devices. Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation"); *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 251, 104 S. Ct. 615, 78 L. Ed. 2d 443 (1984) ("It is difficult (...continued)

asserts that a private right of action, as opposed to a state statute or regulation, is preempted, we are cognizant that preemption may leave individuals with rights but no private remedy, where traditionally there has been one. Although Congress certainly can afford, and in some instances has afforded, federal regulators exclusive jurisdiction over a particular subject matter, and federal regulations will preempt state laws that actually do conflict with them, we do not lightly infer such a result where state compensatory regimes have traditionally played an important role.

Although we are aware that the Supreme Court has applied the presumption in few conflict preemption cases of late, and arguments have been raised that the conflict preemption analysis subsumes or supplants the presumption, *see Colacicco*, 521 F.3d at 265, we will continue to apply the traditional presumption until the Supreme Court provides guidance to the contrary. *Id. See also Hillsborough County*, 471 U.S. at 715 (applying the presumption to implied preemption claims). However, even where the presumption applies it will be overcome where a Congressional purpose to preempt or the existence of a conflict is "clear and manifest." *Id.*

2. Deference to Federal Agency Views

Tri-Union argues that "the FDA's findings and opinion set forth in the FDA Preemption Letter as

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to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

well as its regulatory approach (the FDA Advisory and Backgrounder) should be afforded a high level of deference and/or persuasion." Appellee's Br. at 24.

As we recently explained, "[w]e would ordinarily be leery of an agency's view of what is essentially a legal issue," *Colacicco*, 521 F.3d at 274, but in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000), the Supreme Court "place[d] some weight," on the agency's informal views of the purposes and objectives of the regulation at issue and the agency's view that the state lawsuit would "stand as an obstacle" to those objectives. *Id.* at 883. We concluded that "such a position is subject to a level of deference approximating that set forth in *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 65 S. Ct. 161, 89 L. Ed. 124 [] (1944)." *Colacicco*, 521 F.3d at 275. As with Skidmore deference, the agency's informal views are entitled to "a respect proportional to [their] 'power to persuade' . . . . [Such informal interpretations] claim the merit of its writer's thoroughness, logic and expertness, [their] fit with prior interpretations, and any other sources of weight." *Mead Corp.*, 533 U.S. at 235 (citation omitted). However, *Geier* does not suggest that courts abdicate their duty to examine whether federal and state law actually conflict -- Geier did not rely exclusively on the agency's views, explaining that it found the conflict "clear enough" even absent those views. *Geier*, 529 U.S. at 886.

The District Court concluded that "the FDA's Advisory and Backgrounder are entitled to deference and [] the FDA Letter is persuasive." *Fellner* v. *Tri-Union Seafoods*, 2007 U.S. Dist. LEXIS 1623, 2007 WL 87633, *7 (D.N.J. 2007). Geier and cases

applying it have afforded some weight to an agency's informal interpretation of the purposes and objectives of its regulations which are claimed to preempt state law. However, the FDA's Advisory and backgrounder are not agency interpretations of regulations claimed to preempt state law but rather are the very agency actions which are claimed to preempt state law. We fail to understand how a court could defer to those documents; they offer no interpretation to which we can defer.

The FDA (indirectly) has offered its interpretation of the purposes and objectives of the regulatory measures at issue in this case in the Commissioner's letter. We agree with the District Court that *Geier* directs us to consider the views expressed in that letter and, as we have explained, those views are entitled to consideration proportional to their ability to persuade: "The weight [accorded to an administrative] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all of those factors which give it power to persuade, if lacking power to control." *Mead Corp.*, 533 U.S. at 228 (quoting *Skidmore*, 323 U.S. at 140) (bracketed text in original). Here, however, we do not find the letter persuasive. The circumstances of this letter suggest that it merits a particularly low level of deference. The views the FDA there offers, and the significance it there attributes to its prior administrative actions, have not been shown to be

the product of any agency proceeding,[8] were not expressed at the time those actions were taken nor even at the time that Fellner's damages allegedly arose, and are certainly not self-evident from the nature of the actions themselves. The FDA expressed those views only later, through a most informal of methods -- a letter offering a legal theory for the litigation in California. Most importantly, we simply do not find the letter's reasoning persuasive, for the reasons we set forth below.

C. Tri-Union's Three Theories of Conflict Preemption

As we have explained, this is a conflict preemption case. Therefore, Fellner's state law claims will be impliedly preempted if they are "in actual conflict with federal law." *Sprietsma*, 537 U.S. at 64. The Supreme Court has identified two varieties of "conflict" preemption: (1) where "it is

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[8] The District Court granted the motion to dismiss relying solely on the four documents of which it took judicial notice. Accordingly, our record does not provide a full context for the Commissioner's letter. We can only say that the letter does not itself purport to be the product of an agency proceeding, and the record here does not show it to be. The record in the California litigation does reveal that the Commissioner's letter follows, and bears a striking resemblance to, a letter and memorandum that counsel at a private law firm -- counsel who, according to his public law firm biography, represents the canned tuna industry in the California litigation -- sent to the agency's chief counsel urging the FDA to "issue[] an appropriately worded letter" asserting preemption over the litigation in California and offering suggestions for the content of such a letter. The agency had never before expressed such views. Those views apparently were formulated without the benefit of exposure to conflicting views or critiques.

impossible for a private party to comply with both state and federal requirements," and (2) where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English*, 496 U.S. at 79 (internal quotation marks and citations omitted).

We begin our analysis by taking note of the authority that Congress has bestowed on the FDA and the extent to which it has exercised that authority in a relevant manner. The FDCA grants the FDA authority to regulate the field of food safety. 21 U.S.C. § 371. The FDA has the authority, inter alia, to promulgate food definitions and standards of food quality, *id.* at § 341, and to set tolerance levels for poisonous substances in food. *Id.* at § 346. The FDA is also delegated enforcement authority, including the authority to take various steps to enforce the Act's ban on "adulterated" or "misbranded" food. *Id.* at §§ 331-336, 342-343. The FDA has, however, promulgated no pertinent regulations under this authority. Nevertheless, it has employed various other means to address the risk of mercury in fish, including issuing a consumer advisory and related "backgrounder" regarding those risks, and including in its internal Compliance Guide a provision recommending that the agency initiate enforcement action if mercury concentrations in fish exceed a specified level. TriUnion offers three theories of conflict preemption based on these actions.

1. Theory 1: Conflict with a Federal Regulatory Scheme

Tri-Union first argues that the FDA has adopted a "pervasive regulatory approach" with

which Fellner's lawsuit actually conflicts. Appellee's Br. at 13, 18-20. This argument suffers from two infirmities. First, as we have explained, state law is preempted only by federal law. The FDA has promulgated no pertinent legal standard pertaining either to the risks posed by mercury in fish or to warnings for that risk, and it has not otherwise acted on the issue in a manner that could be deemed an exclusive application of federal law. Second, even accepting arguendo the FDA's "regulatory scheme" were of a type that could preempt state law, Tri-Union has identified no actual conflict between Fellner's claims and the pertinent FDA actions.

We cannot agree with the District Court that the FDA's Advisory and backgrounder "specifically regulate[]" the levels of methylmercury in tuna and "specifically rejected the notion that warning labels should be included on cans of tuna." *Fellner*, 2007 U.S. Dist. LEXIS 1623, 2007 WL 87633 at *4. That Advisory, titled "What You Need to Know About Mercury in Fish and Shellfish," and the related backgrounder, offer "[a]dvice" for "women who might become pregnant[,] women who are pregnant[,] nursing mothers[, and] young children," App. at 35a, and provide "3 recommendations for selecting and eating fish" that such people are advised to follow. *Id.* We are unable to conclude that the Advisory and backgrounder "specifically regulate[]" anything -- they simply give non-binding advice to a class of consumers and do not promulgate a federal legal standard with which Fellner's state law claims could potentially conflict.

Fellner's lawsuit does not conflict with the "advice" in those documents -- the concerns

expressed therein are entirely consistent with, and arguably complementary to, a duty state law may impose on manufacturers to warn consumers of the risks posed by tuna consumption. *See Bates*, 544 U.S. at 449-51. The mere fact that the FDA chose to warn only certain "at risk" consumers, rather than all consumers, does not create a conflict. Nothing in these documents indicates that consumers other than those "at risk" individuals are not at risk of harm from mercury in fish or that they should not be warned. The Advisory does recommend continued fish consumption within certain parameters, but that recommendation is clearly not inconsistent with a warning against excess consumption.

Tri-Union also points to the FDA's internal enforcement guideline suggesting mercury levels which might prompt FDA enforcement action, and the District Court similarly referenced an FDA "tolerance level" of "1 ppm." *Fellner*, 2007 U.S. Dist. LEXIS 1623, 2007 WL 87633 at *2. *See* FDA Compliance Policy Guide, Section 540.600.[9] Based on this guideline, Tri-Union argues that "[t]he FDA has determined that there is no hazard associated with methylmercury concentrations of less than 1 ppm." Appellee's Br. at 37. We find no such determination. Although the FDA has authority to promulgate standards for food quality and tolerance

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[9] Under the heading "Regulatory Action Guidance," this section offers "criteria for recommending legal action to CFSAN/Office of Compliance/Division of Enforcement: The composite analyzed in accordance with the applicable methods . . . shows: Mercury expressed as Methyl Mercury in excess of 1 ppm (edible portion only)." *Id.*

levels for poisonous foods, 21 U.S.C. §§ 341, 346, it has not done so. The internal guideline for allocation of agency resources "recommend[ed]" in the Compliance Policy Guide will not alone preempt state law.

Furthermore, even if this guideline were deemed a federal standard, Tri-Union fails to explain how Fellner's lawsuit would conflict with it. The guideline states that the FDA may recommend enforcement action if methylmercury concentrations in fish exceed "1 ppm." Much like the Advisory, the guideline appears entirely consistent with, and arguably complementary to, a state claim that Tri-Union wrongfully failed to warn consumers of the risks posed by those compounds. We are aware of no facts establishing the precise mercury concentrations in Tri-Union's tuna products. Even if Fellner had alleged a specific concentration lower than the FDA guideline -- for example, if Fellner had specifically averred that Tri-Union's tuna was dangerous because it contained mercury at a concentration of 0.7 ppm -- such a claim would not necessarily be in conflict with this federal "standard." On its face the guideline does not state that tuna with mercury levels below 1 ppm poses no risk nor that a manufacturer has met any particular standard of care if its tuna does not exceed 1 ppm; it merely suggests that the FDA recommend enforcement action if mercury levels exceed 1 ppm.[10]

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[10] Tri-Union's brief before us emphasizes that the FDA has also conducted an educational campaign regarding mercury in fish and that the FDA discussed mercury in its response to a citizen's petition. We have not been asked to take judicial notice (...continued)

In support of its "pervasive regulatory approach" argument, Tri-Union also points to the Commissioner's letter, in which the Commissioner explains that the FDA prefers to address the risks of mercury in fish through advisories rather than warnings requirements due to the risk of overexposure to warnings and the agency's desire to promote moderate fish consumption. We presume that this is a fair concern. However, the FDA has not acted to regulate it in a manner that could preempt Fellner's claims. As we have explained, the letter itself does not establish a federal policy against warnings capable of preempting state law. As we have also explained, we do not find persuasive the letter's characterization of the FDA's prior actions on the subject as a "regulatory scheme" capable of preempting Fellner's claims.

We conclude that the FDA has regulated neither the risk of mercury in tuna nor the permissible warnings regarding that risk in a manner that conflicts with Fellner's lawsuit.

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of these facts, and it is not clear to us that we could do so in the context of a motion to dismiss and a complaint that does not refer to them directly or indirectly. In any event, we fail to see how an educational campaign might preempt Fellner's lawsuit, and we do not read the response to the citizen's petition to speak to a relevant issue. The citizen's petition concerned not the risks of mercury in fish specifically but rather the impact of dietary supplements of "omega-3 fatty acids" on heart disease. It discusses mercury risks only briefly, in the context of mercury's impact on the health effects of omega-3 fatty acids. The FDA merely explained that it would decline to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited.

2. Theory 2: A Federal Decision Not To Regulate

Tri-Union's second theory of preemption is that the FDA has "reject[ed] the use of warning labels," Appellee's Br. at 32 -- that the FDA reached a "federal decision to forego regulation" amounting to "an authoritative federal determination that the area is best left unregulated," a decision which preempts any state standard or duty requiring such warnings. *Id.* at 31 (quoting *Ark. Elec. Co-op.*, 461 U.S. at 384) (emphasis in original). In Tri-Union's view, just such a decision was made when the Commissioner's letter was dispatched. In that letter, the Commissioner expressed the view that, because the FDA after "studying the issue of methylmercury in fish for several years," App. at 42a, declined to require a warning and instead issued an advisory, the California lawsuit would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." *Id.* Although the federal government certainly may promulgate a regulatory regime in which it decides that a particular issue is best left unregulated, as the Supreme Court has explained, "to say that [such a regime] can be created is not to say it can be created subtly." *Isla Petroleum*, 485 U.S. at 500. A mere decision by the FDA not to adopt a federal warnings requirement certainly does not alone preclude states from imposing a duty to warn, and, as we have earlier indicated, we find no authority for the proposition that the FDA could institute a regime affirmatively proscribing all warnings obligations via mere informal expressions of policy such as those in the Commissioner's letter.

Id. at 501, 503 ("[t]here is no federal preemption in vacuo, without a constitutional text or a federal statute to assert it;" "unenacted approvals, beliefs, and desires are not laws").

While the FDA may well have the authority to promulgate a regulatory scheme which would preclude any state duty to warn consumers of the risks of mercury in tuna, it simply has not done so. Tri-Union points to the Commissioner's letter, but as we have explained courts have declined to permit agencies to promulgate express preemption decisions by informal letter. In any event, we do not read the letter as purporting to declare a new preemption policy; it purports to be an explanation of what the FDA determined to do in the past. As we have indicated, however, nothing in the agency's past actions indicates that it made an "authoritative federal determination that the area is best left unregulated."

We have no reason to doubt that the FDA has studied the risks of mercury in fish, as the District Court found. However, it made no "conclusive determination" of the sort which will preempt state law -- neither that mercury in fish poses no adverse health consequences, nor to prohibit some or all warnings. State law is not preempted whenever an agency has merely "studied" or "considered" an issue; state law is preempted when federal law conflicts with state law. As we have explained, the cases leave no doubt that a mere decision not to regulate -- in this case, a decision not to require a federal methylmercury warning -- alone will not preempt state law. *See supra* note 6 and accompanying text. As we have also explained, we find no federal

standard, mandate or regulatory action on the subject with which Fellner's claim conflicts nor any federal determination precluding state regulation of the issue.

3. Theory 3: The FDCA's Food Misbranding Provision

Finally, Tri-Union contends that Fellner's failure-to-warn claim is preempted because that claim is premised on the theory that it should have provided a warning regarding mercury in fish, but the FDA would have deemed any such warning "misbranding," creating a conflict between the asserted state duty and federal law. Appellee's Br. at 33-37. Tri-Union argues that the FDA would deem a warning false and misleading because any such warning would not "specify the scientific basis as to the cause of the harm warned of, and/or the amounts of such food that were required to cause this harm," Appellee's Br. at 34-35, and because a warning would not "balance out the negative methylmercury information with positive information about the numerous healthy attributes of canned tuna," *id.* at 35, resulting in overexposure to warnings and scaring consumers away from a useful product. *Id.* In support of this claim, TriUnion points to the Commissioner's letter, in which the Commissioner opined that the "Proposition 65 warnings" -- the warnings requirement underpinning the California Attorney General's lawsuit -- would be false or misleading for similar reasons.

The FDCA's general misbranding provision for food provides, in pertinent part, that "[a] food shall be deemed misbranded -- (a) False or misleading

label[:] If (1) its labeling is false or misleading in any particular . . . ." 21 U.S.C. § 343(a). FDA regulations further provide that "labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device, or any combination thereof . . . ." 21 C.F.R. § 1.21. The FDCA renders unlawful, inter alia, the misbranding of food and the distribution of misbranded food, *id.* at § 331(a)-(b), and it authorizes the FDA to enforce those prohibitions via enforcement actions in the United States District Courts for injunctions or criminal penalties. *Id.* at §§ 332, 333. The FDCA also delegates to the FDA certain additional tools to prevent misbranding. The FDA may, and indeed must, officially express its concerns with a warning or label before reporting a violation to a United States Attorney for criminal proceedings, to afford the regulated entity notice and an opportunity to present its views. *Id.* at § 335. In the case of "minor violations," the agency may issue "a suitable written notice or warning." *Id.* at § 336. The FDA is also delegated the authority affirmatively to regulate food labels and warnings.[11]

Had the FDA considered the factual basis for the alleged duty to warn and exercised its misbranding authority to establish that a warning

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[11] *See id.* at §§ 341, 346, 371. The FDA has, for certain other foods, exercised this authority by affirmatively requiring particular warnings, *see, e.g.*, 21 C.F.R. § 101.17, but it has not exercised its regulatory authority in any manner pertinent to this case.

based on that data would be false or misleading under federal law -- not merely that the FDA had failed to require the warning, but had exercised its authority specifically to reject it -- our recent decision in *Colacicco* would govern and a state failure-to-warn lawsuit would be preempted. However, Tri-Union's misbranding theory suffers from the same shortcomings as its prior theories: it identifies no regulatory action establishing mercury warnings as misbranding under federal law, and it fails to explain how the regulatory concerns it has identified actually conflict with Fellner's lawsuit.

The FDA has taken no misbranding action pertaining to the risk of mercury in tuna whatsoever. In the above-listed provisions, Congress provided a broad spectrum of ways in which the FDA may act in order to enforce the statutory prohibition on misbranded food -- "a suitable written notice or warning;" an administrative proceeding of the type required to precede a criminal prosecution; a federal court action seeking an injunction or criminal penalties, and affirmative regulation.[12] However, the FDA has taken no action pursuant to this authority. Instead, the FDA merely expressed an informal policy opinion in a letter, and it did so only after Fellner's injuries were allegedly suffered. We need not decide at what point a particular warning becomes established as false and misleading for preemption purposes. Suffice it to say that the FDA must actually exercise its authority in a manner in

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[12] Ultimately, misbranding liability may be imposed only by federal courts.

fact establishing the state warning as false or misleading under federal law; the informal views expressed in the Commissioner's letter will not preempt Fellner's lawsuit.

Furthermore, as with its other preemption theories, TriUnion fails to identify an actual conflict between the FDA's concerns and Fellner's claims. We perceive no actual conflict between those concerns and Fellner's lawsuit. Had Tri-Union wished to warn consumers of those risks, as Fellner alleges it should have, it is not apparent that Tri-Union would have been unable to do so in a manner that satisfied both the alleged state law duty and the FDA's concerns. For example, a warning certainly could have specified that the risks become material only with frequent tuna consumption, and that moderate fish consumption offers positive health benefits. For these reasons, we find no actual conflict between the FDA's misbranding authority and Fellner's lawsuit.

IV. Conclusion

This is a situation in which the FDA has promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect. Fellner's lawsuit does not conflict with the FDA's "regulatory scheme" for the risks posed by mercury in fish or the warnings appropriate for that risk because the FDA simply has not regulated the matter. Fellner's duty-to-warn claim does not conflict with an FDA determination deliberately to

forego warnings because the FDA took no action to preclude state warnings -- at least, no binding action via ordinary regulatory procedures, and no action whatsoever until after Tri-Union allegedly wrongfully failed to warn. Finally, Fellner's lawsuit does not conflict with the FDCA's food misbranding provision or the FDA's actions thereunder because the FDA has not exercised its misbranding authority under the FDCA with respect to methylmercury warnings for fish.

The FDA has only issued a consumer advisory regarding the risks posed by mercury in fish and established a guideline regarding mercury concentrations to guide its enforcement decisions. Neither of these agency acts constitutes a federal legal standard or binding regulatory action on the subject which could give rise to a conflict, and indeed neither expresses a policy or viewpoint or approach inherently inconsistent with Fellner's lawsuit. In the final analysis, this case involves an agency effort to preempt an area of law traditionally within the states' police powers via informal letter, and to do so only after the conduct at issue in this case occurred. We understand the precedent to require more of federal agencies to institute a policy expressly precluding state regulation than a mere informal letter, and neither the Commissioner's letter nor Tri-Union's brief identifies any federal law with which Fellner's lawsuit might conflict. Although the Supremacy Clause provides that state laws will give way when they actually conflict with federal law, on this record we find no federal law with which the alleged state duty to warn conflicts.

For the foregoing reasons, we will reverse the judgment of the District Court and remand the case for further proceedings consistent with this opinion.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEBORAH FELLNER,
Individually and on Behalf of Those Similarly Situated,

Plaintiffs,

v.

TRI-UNION SEAFOODS, L.L.C.,
d/b/a CHICKEN OF THE SEA,

Defendant.

January 8, 2007, Decided

NOT FOR PUBLICATION

DENNIS M. CAVANAUGH, U.S. District Judge

This matter comes before the Court on motion by Tri-Union Seafoods, L.L.C. ("Defendant") to dismiss the complaint of Deborah Fellner ("Plaintiff") and motion requesting judicial notice in support of its motion to dismiss. For the reasons set forth below, Defendant's motions are granted.

BACKGROUND

Plaintiff's Complaint alleges violations of the New Jersey Products Liability Act, N.J.S.A. 2A-58C-

1, et seq., ("NJPLA"), the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq. ("NJCFA") and common law fraud for failing to warn the public that consumption of Defendant's tuna, purportedly containing methylmercury, could result in mercury poisoning. Plaintiff states that her diet consisted "almost exclusively" of canned tuna for five years between 1999 and 2004. She has been diagnosed with mercury poisoning.

Defendant moves for dismissal, arguing that (1) the United States Food and Drug Administration ("FDA") preempts state law in the areas of establishing the maximum allowable concentration of methylmercury in fish and of warning consumers about the potential effects of methylmercury in tuna when consumed; (2) Defendant is not liable under New Jersey law for injuries incurred by Plaintiff for abnormal consumption of its product; (3) New Jersey law does not impose a duty upon Defendant to warn potential plaintiffs about a product that may be dangerous only if over-consumed; and (4) Plaintiff's claim for common law fraud is subsumed by the NJPLA.

DISCUSSION

Motion Requesting Judicial Notice

In support of its motion to dismiss, Defendant requests that this Court take judicial notice of several publicly available reports and articles on methylmercury in fish. The reports are as follows:

- "What You Need to Know About Mercury in Fish and Shellfish," published by the United States Department of Health and Human Services and

the United States Environmental Protection Agency.

- "Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish," published by the United States Department of Health and Human Services ("DHHS") and the United States Environmental Protection Agency. ("EPA").

- Letter from Lester M. Crawford, D.V.M., Ph.D., United States Commissioner of Food and Drugs, to Bill Lockyer, Attorney General of the State of California, dated August 12, 2005, re: a suit filed on June 21, 2004 in San Francisco Superior Court.

- Section 540.600 of the FDA's Compliance Policy Guide allowance of up to one part of methyl mercury per million non-mercury parts of the edible portion of seafood.

Under Federal Rule of Evidence ("FRE") 201, courts can judicially notice public records. *Lum* v. *Bank of America*, 361 F.3d 217, 222 n. 3 (3d Cir. 2004). FRE 201 states:

> A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

Fed. R. Evid. 201

This Court has consistently held that it may take judicial notice of public records on motions to dismiss. *Benak* v. *Alliance Capital Mgmt. L.P.*, 349 F.Supp. 2d 882, 889 n. 8 (D.N.J. 2004) (on motion to dismiss court may take judicial notice of publicly available documents and "plaintiffs may therefore be charged with knowledge of relevant public information."). The articles which the Defendant asks this Court to take judicial notice of are all public records and available. This Court, therefore, grants Defendant's motion that this Court take judicial notice of the publicly available information described above.

Methylmercury in Fish

The nature of this action necessitates consideration of the facts regarding mercury in the environment, methylmercury in fish and the FDA's approach to the issue of methylmercury in fish.

Mercury is present in nearly all fish. *See* "What You Need to Know About Mercury in Fish and Shellfish," U.S. Dept. of Health and Human Serv. and the United States Envtl. Prot. Agency EPA-823-R-04-005 (March 2004) (hereinafter "The Advisory"). Mercury is a naturally occurring element in the environment and is also released into the air through industrial pollution. *Id.* Mercury that falls from the air often accumulates in streams, oceans and other bodies of water. *Id.* Fish absorb the mercury as they feed in these waters. *Id.* As a result, mercury becomes part of the fish meat and cannot be removed. *Id.*

The FDA has established tolerance levels for methylmercury in fish through nutritional

guidelines. *See* Fed. Food and Drug Admin. Compliance Policy Guide, § 540.600 (May, 2005). The FDA has also noted that "[r]esearch shows that most people's fish consumption does not cause a health concern." *See* Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish at p. 2 (2004) (hereinafter, "Backgrounder"). Additionally, the FDA states that "[f]ish and shellfish can be an important part of [a recommended] diet." *Id.* at 2-3.

Motion to Dismiss

Legal Standard for Granting a Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a complaint "for failure to state a claim upon which relief can be granted." In deciding a motion to dismiss under Rule 12(b)(6), all allegations in the complaint must be taken as true and viewed in the light most favorable to the plaintiff. *Warth* v. *Seldin*, 422 U.S. 490, 501, 95 S. Ct. 2197, 45 L. Ed. 2d 343 (1975); *Trump Hotels & Casino Resorts, Inc.* v. *Mirage Resorts, Inc.*, 140 F.3d 478, 483 (3d Cir. 1998). However, legal conclusions offered in the guise of factual allegations are given no presumption of truthfulness. *Chugh* v. *Western Inventory Serv., Inc.*, 333 F. Supp. 2d 285, 289 (D.N.J. 2004) (citing *Papasan* v. *Allain*, 478 U.S. 265, 286, 106 S. Ct. 2932, 92 L. Ed. 2d 209 (1986)). While a court will accept well-pled allegations as true for the purposes of the motion, it will not accept bald assertions, unsupported conclusions, unwarranted inferences or sweeping legal conclusions cast in the form of factual allegations. *Morse* v. *Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997).

Claims Under New Jersey Product Liability and Consumer Fraud Acts

Plaintiff's complaint alleges violations of the NJPLA and NJCFA on behalf of herself individually and on behalf of those similarly situated. The allegations are that Defendant knowingly misrepresented, concealed, suppressed, omitted and failed to disclose material information regarding the presence of methylmercury and other harmful compounds in their tuna products with the intent that Plaintiff and members of the class rely upon such concealment. The complaint also accuses Defendant of negligence, breach of the implied warranty of fitness, and strict liability for failure to adequately warn consumers about the mercury compounds contained in its products.

Defendant argues for dismissal of Plaintiff's complaints under the NJCFA and NJPLA because they are preempted by FDA regulations and advisories which specifically address and regulate the issues of allowable amounts of mercury in its product and whether or not the Defendant is required to warn consumers of the dangers of mercury consumption.

The basis for federal preemption is the Supremacy Clause of the Constitution. *Dewey* v. *R.J. Reynolds Tobacco Co.*, 121 N.J. 69, 77, 577 A.2d 1239 (1990). The clause provides that federal law is the "supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. This preemption applies equally to state common law and statutory law. *Feldman* v. *Lederle Lab.*, 125 N.J.

117, 134, 592 A.2d 1176 (1991) *cert. denied*, 505 U.S. 1219, 112 S. Ct. 3027, 120 L. Ed. 2d 898 (1992).

Whether a federal statute preempts state law turns on the intent of Congress when it passed the law and that intention may be either express or implied. *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992). Federal law overrides state law when (1) Congress expressly preempts state law; (2) Congressional intent to preempt can be inferred from the existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes. *English* v. *General Elec. Co.*, 496 U.S. 72, 78-79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990).

In this case, there is a pervasive federal regulatory scheme implemented by and through the FDA. The FDA has stated that state laws which require warnings regarding methylmercury in fish are preempted under federal law. *See* Letter from Lester M. Crawford, D.V.M., Ph.D., United States Commissioner of Food and Drugs ("Commissioner Crawford"), to Bill Lockyer, Attorney General of the State of California, dated August 12, 2005, re: a suit filed on June 21, 2004, in San Francisco Superior Court ("FDA Letter").

On June 21, 2004, the Office of the Attorney General of California filed suit seeking an injunction and civil penalties against the Tri-Union Seafoods, LLC, for failing to warn consumers that canned and packaged tuna products were exposing consumers to mercury compounds. *The People of the State of California* v. *Tri-Union Seafoods, LLC, et al.*, 2006 WL 1544377 (Cal. Super. Case No.: CGC-04-432394). In response to the suit, Commissioner Crawford

wrote the FDA Letter which explained that the warnings sought by California would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." *See* FDA Letter at p. 1.

The FDA Letter also explained that the "FDA has been studying the issue of methylmercury in fish for several years. In so doing, it has compiled substantial data, and has developed significant expertise in analyzing the pertinent scientific issues, together with the consumer education aspects of this matter. As a result, the agency believes that it is uniquely qualified to determine how to handle the public health concerns related to methylmercury in fish. After many years of analysis on this issue, [the] FDA has chosen to issue an advisory rather than to require a warning on fish and shellfish product labels for several reasons." *See* FDA Letter at p. 2.

The FDA issued its 2004 methylmercury advisory to, "inform women who may become pregnant, pregnant women, nursing mothers, and parents of young children as to how to get the positive health benefits from eating fish and shellfish, while minimizing their mercury exposure." *See* FDA Letter at p. 4. The Advisory specifically regulates the levels of methylmercury allowed in canned tuna and specifically rejected the notion that warning labels should be included on cans of tuna. *Id.*

Plaintiff argues that the FDA does not preempt New Jersey state law for failure to warn of the dangers of mercury in the Defendant's tuna. There is a presumption in the law against preemption. *New York Conference of Blue Shield*

and Blue Cross Plans v. *Travelers Ins. Co.*, 514 U.S. 645, 655, 115 S. Ct. 1671, 131 L. Ed. 2d 695 (1995). The burden is on the proponent of preemption to overcome the presumption against finding that areas traditionally regulated by the states, such as products liability or consumer protection laws, have been preempted. *Hillsborough County* v. *Automated Med Lab.*, 471 U.S. 707, 716, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985).

Plaintiff suggests that the Defendant has failed to carry its burden to overcome the presumption against a finding that either the NJPLA or NJCFA have been preempted by the FDA's actions. In support of its position, Plaintiff states that The Advisory and Backgrounder are not entitled to deference and that the FDA Letter is not persuasive.

Plaintiff explains that the FDA has not officially prohibited mercury warnings on cans of tuna regarding methylmercury. For this proposition, Plaintiff argues that the FDA Letter is not entitled to deference from this Court. "Interpretations contained in formats such as an opinion letter are entitled to respect, . . . but only to the extent that those interpretations have the power to persuade." *Christensen* v. *Harris County*, 529 U.S. 576, 587, 120 S. Ct. 1655, 146 L. Ed. 2d 621 (2000).

The New Jersey Supreme Court ruled that the lack of a formal FDA requirement for additional warnings on a product does not create a conclusive presumption that labeling which satisfies the FDA also constitutes an adequate warning under state law. *Feldman* v. *Lederle Lab.*, 125 NJ 117, 592 A.2d 1176 (NJ 1991), *cert. den.*, 505 U.S. 1219, 112 S. Ct.

3027, 120 L. Ed. 2d 898 (1992). As such, if this Court finds that the FDA's regulatory scheme, as described in the Advisory and Backgrounder, is not entitled to deference and that the FDA Letter is not persuasive, then Defendant could comply with both New Jersey and federal law by placing warning labels on their tuna products.

The essential issue is whether the FDA's regulatory scheme as explained and embodied in the FDA Letter, Advisory and other materials is entitled to deference from this Court. In arguing that this Court should not defer to the FDA's interpretation of its regulatory scheme in this area, Plaintiff points to the FDA Letter and calls it too informal. In her brief, Plaintiff states that the FDA Letter "appears to have been solicited for the express purpose of derailing litigation against [Defendant] and other seafood companies." Therefore, Plaintiff reasons, the FDA Letter and arguments contained therein are not the product of independent analysis by the FDA, but are simply the parroting of arguments designed to benefit the Defendant and other industry members in this and other potential lawsuits.

An examination of the FDA's response to the potential health hazards of methylmercury in food reveals that the FDA has been collecting data and addressing this concern for years. The FDA issued its first methylmercury fish advisory in the mid 1990s. *See* FDA Letter at p. 3. Since that time, the FDA has compiled more data and has developed significant expertise in analyzing the scientific issues and consumer education aspects of this matter.

After studying the data, the Foods Advisory Committee ("FAC") recommended that the FDA and

EPA jointly issue an advisory about mercury in fish for women who might become pregnant, women who are pregnant, nursing mothers and young children. *See* Advisory at p. 1.

On March 19, 2004, the FDA and EPA released The Advisory, with the following message:

> Message to Consumers:
>
> Fish and shellfish are important parts of a healthy and balanced diet. They are great sources of high quality protein and other nutrients. However, depending on the amount and type of fish you consume it may be prudent to modify your diet if you are planning to become pregnant; pregnant; nursing; or a young child. With a few simple adjustments, you can continue to enjoy these foods in a manner that is healthy and beneficial and reduce your unborn or young child's exposure to the harmful effects of mercury at the same time.

See Advisory at p. 1.

The Backgrounder to the Advisory, released simultaneously, clearly emphasizes the importance of continuing to eat fish as part of a healthy diet:

> The Difference Between this Advisory and Previous Advisories:
>
> 1. The advisory emphasizes the positive benefits of eating fish.
>
> 2. The advisory provides examples of commonly eaten fish that are low in mercury.

* * *

What's Next:

FDA and EPA want to ensure that women and young children continue to eat fish and shellfish because of the nutritional benefits and encourage them to follow the advisory so they can be confident in reducing their mercury exposure as well.

See Backgrounder at p. 2.

Plaintiff argues that the FDA Letter is merely an *ex parte* communication intended to derail litigation against the seafood industry. However, the FDA Letter aside, both the Advisory and Backgrounder excerpted above were released in March, 2004. The California litigation to which the FDA Letter responds commenced on June 21, 2004. Therefore, the Advisory and Backgrounder which evidence a clear effort by the FDA and EPA to encourage the continued public consumption offish, were released before the complaint in the California case had even been filed. Clearly, the FDA had already taken the position against blanket warning labels before the California suit which prompted the FDA Letter.

In advocating the position that the Advisory and Backgrounder have no preemptive effect on the NJCFA and NJPLA, Plaintiff argues that the mere existence of a federal regulatory or enforcement scheme does not by itself imply preemption. *English.*, 110 S. Ct. at 2279 (1990). Plaintiff's opposition to Defendant's motion to dismiss characterizes the Advisory and Backgrounder as

"minuscule" actions which are not official regulations and, therefore, not sufficient to preempt state law.

However, it is not uncommon for the FDA to specifically choose the issuance of an advisory rather than an official warning In his letter to the California Attorney General, Commissioner Crawford explained, "[f]irst, consumer advisories are communicated to the target audience directly, rather than to all consumers. Second, the FDA believes that the advisory approach is more effective than a product label statement in relaying the complex messages about mercury in seafood. Third, a label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results have suggested that people who are not in the target audience . . . might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish . . ." FDA Letter at p. 2-3.

In holding that a formal explicit agency statement is not necessary for the finding of a preemptive intent, the Supreme Court of the United States explained,

> "the Court has never before required a specific formal agency statement identifying conflict in order to conclude that such a conflict in fact exists. Indeed, one can assume that Congress or an agency ordinarily would not intend to permit a significant conflict.

Geier v. *Am. Honda Motor Co.*, 529 U.S. 861, 884-85, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000).

In *Geier*, the Supreme Court of the United States examined the Department of Transportation's interpretation of the regulation at issue's objectives and the Department's conclusion that tort suits, like the suit against American Honda Motor Co., would stand as an obstacle to the accomplishment and execution of those objectives. The Court reasoned that "the agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." *Id.* at 883 (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 496, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)).

Deference to an agency's interpretation of its own powers is appropriate when the regulatory scheme is silent as to preemption. *Barnhart* v. *Thomas*, 540 U.S. 20, 26, 124 S. Ct. 376, 157 L. Ed. 2d 333 (2003). Here, the FDA Letter in response to the California litigation only crystallizes the already transparent intent of the FDA to preempt state law that might interfere with the FDA's concern that warnings on tuna products may upset the desired balance between informing consumers of both the benefits and risks of fish consumption:

> [The] FDA believes that such warnings are preempted under federal law. They frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish; accordingly federal law preempts [California's] warnings concerning mercury and mercury compounds in tuna. Furthermore, [the] FDA believes that

> compliance with both the FDA and [the California warning] is impossible and, as a result, the latter is preempted under federal law.

See FDA Letter p. 1-2

Commissioner Crawford also explained that, "rather than requiring warnings for every single ingredient or product with possible deleterious effects, the FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information...in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements, and hence creating a far greater public health problem." *Id.*

For the reasons discussed above, this Court finds that the FDA's Advisory and Backgrounder are entitled to deference and that the FDA Letter is persuasive. Therefore, applying the carefully structured and implemented regulatory scheme of the FDA to Plaintiff's allegations that Defendant was required by New Jersey law to provide warnings about methylmercury and that Defendant's failure to warn constituted a violation of the NJCFA, shows that it would be impossible for Defendant to comply with the FDA and New Jersey law.

It is worth noting that the FDA's regulatory approach has been in effect and has preempted New Jersey state law for the entire period that the Plaintiff's diet consisted almost exclusively of canned tuna (1999-2004). The FDA's published its first methylmercury in seafood advisory in the mid-1990s. *See* FDA Letter at p. 3.

The FDA's regulatory scheme is the result of over ten years of data collection and study. Plaintiff suggests that this Court dismiss the FDA's analysis and deliberately nuanced response to the issue of methylmercury found in seafood. To ask that this Court ignore the evidence of the FDA's carefully balanced approach in favor of Plaintiff's claim that the FDA's treatment of this issue is a contrived response to potential lawsuits against the seafood industry distorts logic. This Court will not turn a blind eye to the evidence of the FDA's ten-year deliberately balanced approach to the issue of methylmercury in fish.

This Court, therefore, grants Defendant's motion that Counts I, II and III of Plaintiff's complaint be dismissed.

Claims Under Common Law Fraud

Plaintiff alleges that the actions of Defendant constitute fraudulent conduct, including but not limited to, knowingly making material misrepresentations and omissions regarding Defendant's tuna products upon which Plaintiff reasonably relied. Defendant argues that Plaintiff's common law fraud claims must be dismissed because they are subsumed by the NJPLA.

In *Estate of Brown* v. *Philip Morris, Inc.*, 228 F. Supp. 2d 506 (D.N.J. 2002), the decedent's wife brought suit against three cigarette manufacturers asserting that smoking resulted in the death of her husband and alleging both a violation of the NJPLA and common law fraud. *Id.* The court held that the NJPLA "clearly subsumes plaintiff's common-law claims." *Id.* at 516. Put another way, plaintiffs

cannot recast a product liability claim as a fraud claim. *Walus* v. *Pfizer, Inc.*, 812 F.Supp. 41, 45 (D.N.J. 1993).

Count IV of Plaintiff's complaint alleges common law fraud asserting exposure to "unsafe methylmercury and other harmful compounds that could result in mercury poisoning." Counts I and II allege a violation of the NJPLA. As was the case in Estate of Brown, Plaintiff merely "recasts [her] product liability claims" as fraud claims.

Plaintiff's common law fraud claim is pled in violation of the NJPLA's single cause of action rule. This Court, therefore, grants Defendant's motion that Count IV of Plaintiff's complaint be dismissed.

CONCLUSION

Based on the foregoing, Defendant's Motion to Dismiss Plaintiff's complaint is granted. An appropriate Order accompanies this Opinion.

/S Dennis M. Cavanaugh, U.S.D.J.

Date: Jan. 8, 2007

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 07-1238

DEBORAH FELLNER, individually and
on behalf of those similarly situated

v.

TRI-UNION SEAFOODS, L.L.C.
d/b/a CHICKEN OF THE SEA;

Deborah Fellner,
Appellant

SUR PETITION FOR REHEARING

BEFORE: SCIRICA, Chief Judge, SLOVITER, McKEE, RENDELL, BARRY, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, HARDIMAN and STAPLETON,*
Circuit Judges

The petition for rehearing filed by appellee in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in

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* Senior Circuit Judge Walter K. Stapleton was a member of the original panel. His vote is limited to panel rehearing.

regular active service not having voted for rehearing by the court en banc, the petition for rehearing is denied.

By the Court,

/s/ Walter K. Stapleton
Circuit Judge

Dated: 15 September 2008

Relevant Provisions Of The Food, Drug, And Cosmetics Act, 21 U.S.C. § 301 *et seq.*

§ 321. Definitions; generally

* * *

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

* * *

§ 343. Misbranded food

A food shall be deemed to be misbranded--

(a) False or misleading label. If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 [21 U.S.C. § 350] applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2) [21 U.S.C. § 350(b)(2)].

* * *

(f) Prominence of information on label. If any word, statement, or other information required by or under

authority of this Act [21 U.S.C. §§ 301 et seq.] to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

* * *

(v) Failure to label; health threat. If--

(1) it fails to bear a label required by the Secretary under section 801(n)(1) [21 U.S.C. § 381(n)(1)] (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner or consignee involved that the label is required under section 801 [21 U.S.C. § 381], the Secretary informs the owner or consignee that the food presents such a threat.

* * *

§ 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce--

(1) any requirement for a food which is the subject of a standard of identity established under section 401 [21 U.S.C. § 341] that is not identical to such standard of identity or that is not identical to the

requirement of section 403(q) [21 U.S.C. § 343(q)], except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 401 and 403(g) [21 U.S.C. §§ 341 and 343(g)],

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), 403(i)(2), 403(w), or 403(x) [21 U.S.C. § 343(c), (e), (i)(2), (w), or (x)] that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(c) [21 U.S.C. § 343(c)] and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) [21 U.S.C. § 343(b), (d), (f), (h), (i)(1) or (k)] that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(h)(1) [21 U.S.C. § 343(h)(1)] and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) [21 U.S.C. § 343(q)], except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A) [21 U.S.C. § 343(q)(5)(A)(i) or (ii)], or

(5) any requirement respecting any claim of the type described in section 403(r)(1) [21 U.S.C. § 343(r)(1)] made in the label or labeling of food that

is not identical to the requirement of section 403(r) [21 U.S.C. § 343(r)], except a requirement respecting a claim made in the label or labeling of food which is exempt under section 403(r)(5)(B) [21 U.S.C. § 343r(5)(B)].

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990 [note to this section].

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that--

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by, the requirements of the sections referred to in subsection (a).

§ 346. Tolerance for poisonous or deleterious substances in food; regulations

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [21 U.S.C. § 342(a)(2)(A)]; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of

public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [21 U.S.C. § 342(a)(2)(A)]. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a) [21 U.S.C. § 342(a)(1)]. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

Relevant Provisions Of The Nutrition Labeling And Education Act of 1990, 104 Stat. 2353

* * *

[Sec. 6] (c) CONSTRUCTION.

(1) The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act.

(2) The amendment made by subsection (a) and the provisions of subsection (b) shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning

concerning the safety of the food or component of the food.

(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.

* * *